Whole Systems Healthcare: Traditional Chinese Medicine Acupuncture under the Microscope

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ACKNOWLEDGEMENTS

'There is no such thing as a "self-made man". We are made up of thousands of others. Everyone who has ever done a kind deed for us, or spoken one word of encouragement to us, has entered into the makeup of our character and of our thoughts, as well as our success.'

George Matthew Adams, Writer.

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I dedicate this thesis to my daughter and in memory of my dad who always encouraged me to work hard academically and shaped my world.

DECLARATION

I grant powers of discretion to the University Librarian to allow this thesis to be copied, in whole or in part, without further reference to me. This permission covers only single copies made for study purposes, subject to normal conditions of acknowledgement.

SECTION A - PREFACE

This portfolio is a demonstration of the skills and knowledge I have acquired while training for the Professional Doctorate in Health Psychology and it documents evidence of how I have acquired the relevant competencies. I have gained generic psychological skills while working in the Public Health Department (Stop Smoking Service) within the National Health Service (NHS) Primary Care Trust; I have held posts of Family Health Advisor, Stop Smoking Advisor and Primary Care Facilitator and my duties have included consultancy, research, implementing psychological interventions and directing the implementation of interventions.

My clinical duties have included the delivery of evidence-based smoking cessation advice to individuals and groups; utilising both psychological and pharmacological treatment approaches have been central to my role as a practitioner psychologist within the smoking cessation field; among other professional activities I have provided advice in individual (face-to-face) and group contexts within a structured program of activity over a period of seven weeks. The psychological and behavioural management tools I have employed in my work have included motivational interviewing (Miller & Johnson, 2001) for client motivation to engage in long term behaviour change; interventions are matched to clients' readiness to change and influenced by the stages of change (DiClemente et al., 1991), theory of planned behaviour (Ajzen, 1985), and self-efficacy (Bandura, 1977) models. I have also utilised a bio-psychosocial model of addiction to gauge client beliefs about their smoking behaviour, social contexts and coping mechanisms; the main components of the intervention are cognitive behavioural therapy (CBT) and withdrawal-oriented therapy. I have provided clients with advice on the biological aspects of nicotine addiction and its interaction with psychological aspects of addiction, and I have also provided advice on relapse prevention.

In my role as a smoking cessation specialist I have trained and supervised healthcare professionals providing them with on-going advice, education, guidance and support on the psychological component of smoking cessation treatments. I have extracted a great deal of benefit, learning and enjoyment from my involvement in promoting individual and population health and wellbeing, and working in this context has afforded me the opportunity to consolidate my skills and expertise as a practitioner psychologist.

My research area of interest is Complementary and Alternative Medicine (CAM) and my research competence (comprising one main piece of research and a systematic review) are in this area. The main research study is an investigation of the efficacy of one particular style of acupuncture, i.e. Traditional Chinese Medicine Acupuncture (TCMA); my systematic review is in the area of mindfulness-based interventions, specifically Mindfulness Based Stress Reduction (MBSR) and Mindfulness Based Cognitive Therapy (MBCT), delivered within an oncological setting.

The portfolio begins with the research thesis and then introduces each of the five competencies that demonstrate my professional competence as a practitioner psychologist; the systematic review is presented in the final section.

The main research study is the first to employ a 'Whole Systems Research' (WSR) methodology (Ritenbaugh et al., 2010), to explore the effectiveness of Traditional Chinese Medicine Acupuncture (TCMA) treatment delivered in a clinic setting to patients presenting with a wide range of health conditions and coming from a wide range of socioeconomic backgrounds, but most significantly including a majority of people from lower socioeconomic backgrounds. The study employed a WSR design involving quantitative research (study 1) and qualitative research (study 2) to examine the effect of TCMA, and the aim of the research was to provide a greater depth of understanding about the perceived experiences and effects of TCMA treatment in relation to patient health, wellness and quality of life.

It was hoped that the research outcomes will contribute to the efficacy body of knowledge on TCMA, including knowledge of possible variations in TCMA outcome in relation to a patient population with both a diverse profile of socio-demographic characteristics and a wide range of health conditions. The primary objective of study 1 was to explore TCMA efficacy by investigating changes in patient health outcomes over time, as recorded by patients in the Measure Yourself Medical Outcome Profile (MYMOP) (Paterson, 1996), i.e. recorded changes in primary symptom, activity and well-being, over six weeks. A secondary objective of study 1 was to explore potential variations in TCMA outcome in relation to both patients' socio-demographic characteristics, i.e. age, gender, ethnicity and socioeconomic statue (SES), and the wide range of health conditions reflected in the sample. Study 2 explored TCMA patient perceptions and experiences of treatment efficacy in terms of health, wellness and quality of life.

Patients in this research study reported beneficial outcomes that are closely related to symptoms of their presenting conditions, including: symptom improvement, pain relief, more energy and strength, and positive changes in emotional, cognitive and physical functioning; and they also reported beneficial outcomes that are more broadly related to well-being, including: increased energy levels, more spirituality and spiritual harmony, 'better connection', improved psychological awareness, peace and relaxation, better levels of personal happiness and optimism, improved motivation and perceived self-efficacy. It is also noteworthy that patients reported unexpected personal growth and development in different dimensions of their lives. The findings from this study, which are consistent with research on both important domains in TCMA (Verhoef, 2006) and 'expanded effects', present a number of interesting practical implications to improve healthcare practice in healthcare settings.

The second part of this portfolio presents five case studies that demonstrate my professional practice, the first of which is 'Generic professional competence' in health psychology and it details professional practice in terms of the legal, ethical and professional standards of the British Psychological Society and the NHS service. Examples are presented of implementing this practice within my day to day work within a large Public Health Department. The competence case study further demonstrates my competence in providing psychological guidance and feedback within my role and ways in which I continually develop my professional practice.

The second case study presents consultancy competence demonstrated when my services as a trainee health psychologist were contracted on behalf of a specialist service (located within the Public Health Department) that provides acupuncture services within general practices in the borough (I was offered the opportunity to do this consultancy as a result of my interest in CAM and acupuncture). In this consultancy my brief was to investigate i. GP satisfaction with the service and ii. the referral patterns, the aim of which was to identify the cost effectiveness of the service. The impact of this consultancy was to increase both the awareness of the acupuncture service in [redacted] and the number of GP referrals to the service as well as making a contribution to the planning and targeting of resources and the procurement of additional resources.

The third case study demonstrates my teaching and training competence; my work routinely involved training health professionals to counsel in smoking cessation

and this case study details the training I delivered to two different groups of health professionals, i.e. midwives and pharmacists.

My fourth case study presents my first optional competency, implementing psychological interventions. Providing advice, based on psychological and behavioural change theory, to smokers who want to stop smoking is a routine part of the work I was employed to do, and this case study provides details of this competence in action; regular face to face contact with clients over a 6 to 7-week period to ensure they are being supported during the most difficult periods when cravings to smoke are at their strongest. The intervention is evidence based and employs the following psychological theories and applications; withdrawal-oriented therapy, cognitive behaviour therapy, motivational interviewing, relapse prevention, and the stages of change model.
The fifth case presented is the optional competency, directing the implementation of interventions. Setting up smoking cessation services within the borough, which is a multi-level process that involves training health professionals to deliver smoking cessation services, is a routine element of the work I have completed; training involves presenting and explaining the psychological components of the intervention to health professionals, establishing and monitoring the service and providing ongoing training and specialist supervision.

The last section of this portfolio is a systematic review that investigate patients' perceptions and experiences of Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT) as adjunctive treatments for cancer patients. Systematic reviews of MBSR (and MBCT) in oncology have documented how these interventions are effective for improving mood, sleep, fatigue, psychological functioning, psychosocial adjustment, stress management, enhanced coping and well-being in cancer patients (Shennan, Payne & Fenlon, 2011). The meta-synthesis completed in this systematic review offers the clinician an integrated and more complete interpretation of findings on cancer patients' perceptions and experiences of MBIs than was previously available and alludes to the possible mechanisms by which the program effects its beneficial health outcomes. The 'Challenge' theme is of particular interest because it focuses attention on activities that some participants find challenging, most notably independent home meditation practice. Such difficulties may undermine the documented health and wellbeing impact of MBI, and the challenge theme, by highlighting these areas of potential difficulties, provides insights regarding strategies for improving the program's effectiveness. More research is needed to

increase our understanding of participant characteristics and influence on MBI program effectiveness.

Finally, working within the NHS Public Health Department for 10 years has provided me with many years of experiences and opportunities to demonstrate my skills as a trainee practitioner health psychologist and I have enjoyed and benefitted from the opportunities that this has afforded me.

SECTION B – RESEARCH

ABSTRACT

Aim

The aim of this study was to investigate the efficacy of a specific school of acupuncture, Traditional Chinese Medicine Acupuncture (TCMA), as a whole complex intervention, as it operated in a clinic setting, on a wider representation of users and spectrum of diseases than the typical acupuncture user profile, and to explore potential variations in health outcomes.

Design and Setting

This was a retrospective study that employed a Whole Systems Research (WSR) design that involved outcome evaluation, to determine the efficacy of TCMA, together with process evaluation, to determine patient perceptions of how the intervention worked in practice, with regards to health, wellness, and Quality of Life (QoL).

The research focused on a subsidised clinic that was located in a socially deprived area of London.

Methods

The retrospective study period was February 2007 to March 2008. Scores from Measure Yourself Medical Outcome Profile (MYMOP), an outcome measure used to investigate changes in health outcomes over time, were extracted from individual patient files (N=208) that had fulfilled the inclusion criteria of attendance at six consecutive treatment sessions, delivered from baseline treatment, irrespective of outcome or symptom.

MYMOP scores on Symptom, Activity and Wellbeing, that were completed at baseline (treatment 1) follow up (treatment 2), follow up (treatment 3), follow up (treatment 4), follow up (treatment 5) and follow up (treatment 6), were analysed using repeated measures ANOVA to investigate whether a significant difference in QoL, a variable derived from the mean of the nominated MYMOP scores, existed between baseline treatment and outcome for patients over the six week treatment period; statistical analysis was also completed to explore variations in treatment outcomes in

relation to patient's socio-demographic characteristics, age, gender, ethnicity and social grade, and the wide range of health conditions reflected in the sample.

Written patient commentaries (N=117), concerning experiences of TCMA, that were provided on patient discharge forms were extracted and analysed using Thematic Analysis.

Results

Significant differences were found in the direction of better reported MYMOP Symptom, Activity and Wellbeing scores following TCMA treatments and a significant difference in QoL was found between baseline assessment and outcome for TCMA patients over the 6-week course of treatment.

Statistical analysis produced no evidence that the perceived benefits of TCMA treatment were associated with patients' gender, age, ethnicity, social class, or presenting condition; no evidence was found that either demographics or presenting condition operated as outcome modifiers.

Thematic analysis resulted in the identification of five themes which together provided insight into, and a way of understanding, both the outcomes and the processes that operated within TCMA.

Conclusion

Findings from the present study show that TCMA delivered perceived global and multidimensional beneficial changes in health, wellbeing and QoL; furthermore, the perceived positive treatment outcomes, which were unrelated to illness type or severity at the time of initial treatment, were consistent across socio-demographic subgroups and a wide spectrum of challenging cases of both physical and mental pathology.

The study's findings are important because they have advanced understanding of TCMA treatment efficacy and the workings of this particular style of acupuncture (TCMA) in terms of health, wellness and QoL.

CHAPTER 1

Introduction

This Chapter provides the background to the research, explains why the research was carried out and highlights the unique contribution of the present study to the field of Complementary and Alternative Medicine (CAM) in general, and Traditional Chinese Medicine Acupuncture (TCMA) specifically. The rationale for the present study is explained together with the significance of, and justification for, the study.

This chapter provides an overview of the health psychology literature pertaining to CAM and attempts to explain how and why it has become such a substantial phenomenon in healthcare; CAM provides a context in which the theoretical underpinnings of healthcare are very different to those of mainstream medicine and it therefore offers opportunities to investigate key issues in health care from a different perspective. Following discussion of CAM in general, the chapter focuses in on TCMA, a CAM therapy that has a number of features that make it a suitable target for a study of this kind; i.e. it is an international therapy, provided by trained practitioners, with widely available treatment centres and it enjoys recognition and advocacy within the mainstream health professions. The chapter also provides an overview of the philosophical and practical issues associated with evaluating TCMA and CAM, and it outlines why the research efforts are needed in these fields.

Complementary and Alternative Medicine (CAM)

CAM is a health-related service that has, for many years, operated alongside mainstream medicine in many countries around the world, including the UK, the USA and Australia (Ernst, 2000); Van Wersch (2009) reported that the use of CAM was 'increasing exponentially in western countries' and more recently Jakes, Kirk and Muir (2014) described its use as 'widespread'. Regarding CAM use in the UK, Posadzki and colleagues found that, in terms of average one-year prevalence of use, at least 25% of the population have used CAM, and in terms of average life-time use over 40% of the population have used it, (Posadzki, Watson, Alotaibi, & Ernst, 2013).

Defining CAM. Defining what CAM is has proven to be an elusive goal; according to Long (2013) attempts to define CAM have fruitlessly focused on various CAM modalities including: mind-body interventions such as yoga and meditation;

energy-related modalities such as acupuncture and shiatsu; body alignment interventions such as osteopathy and chiropractic; herbal medicine; and, nutrition. Long presented a 'commonly cited definition', i.e. that CAM is, 'a group of diverse medical and healthcare systems, practices and products that are not presently considered to be part of conventional (bio-) medicine'; Long also cited the definition within the Cochrane Collaboration where complementary medicine is defined as, 'include (ing) all such practices and ideas which are outside the domain of conventional medicine in several countries and defined by its users as preventing or treating illness, or promoting health and well-being' (Long, 2013, p. 3).

There is, however, no universally accepted definition of CAM (NHS Choices, 2016); furthermore, the utility of the various definitions that have emerged over the years has been questioned because of a tendency to define CAM not by 'what it is' but by 'what it is not' (Coulter and Willis, 2004). The two definitions above, presented by Long, are typical of this practice, which is also evident in the current NHS definition, 'treatments that fall outside of mainstream healthcare', (NHS, 2016).

As observed by Long (2013) all of these various definitions (and more) have appeared in the literature and in discussions on policy and practice, a fact that has had a negative impact on some research findings; for example, Bishop and Lewith (2010) reported that, in part, the lack of agreement on how CAM was defined in the various papers they reviewed for their study contributed to their inability to draw conclusions about the relationship between CAM use and ethnicity; other researchers have also commented on how studies of CAM use show 'considerable variability' due to definitional problems (Ernst & White, 2000; Thomas et al., 2001).

An understanding of CAM has been facilitated to some extent by the use of classification systems, for example, Pietroni (1992) identified four major CAM domains, as follows: 'complete systems', these work with a particular paradigm and have unique diagnostic methods and approaches to treatment, included in this category are osteopathy, homeopathy, acupuncture and herbal medicine; 'diagnostic approaches', which includes iridology and hair analysis; 'therapeutic modalities', which includes massage, shiatsu and reflexology and 'self-care approaches', which includes a range of approaches to personal self-care.

Why CAM is the preferred term. The CAM modalities that are listed in classification systems such as Pietroni's were historically referred to by various labels the most common of which was 'alternative medicine' (Vincent & Furnam, 1998);

according to a number of researchers the significance of the added term 'complementary', in the title 'Complementary and Alternative Medicine', is the implication that CAM is a supplement to and/or offers support for conventional mainstream medicine, which has been considered important for establishing its credibility alongside mainstream medicine (Long, 2013; Eisenberg et al., 1993; Thomas et al., 1991; Cassileth, 1989; Moore et al., 1985). Long (2013) argued that the idea that CAM is complementary to, and not just alternative to, mainstream medicine was important because it is a dimension that has widened the choices that individuals have for resolving their health problems, managing their ill-health and promoting their health and well-being.

Although CAM is the generally accepted term, a distinction between the two terms 'complementary' and 'alternative' has often been made; for example, the US National Centre for Complementary and Integrative Health (NCCIH) suggested that 'complementary' means that CAM could be used together with conventional medicine, and 'alternative' means that it could be used instead of conventional medicine, although it was acknowledged that any one CAM approach could be used as either an alternative or a complementary therapy (NHS Choices website, 2016).

Differences between CAM and Mainstream Medicine

CAM is separate from and fundamentally different to traditional mainstream medicine, so much so that the two systems are sometimes directly opposed to each other (Ernst and Cassileth, 1994); Bell and Koithan (2006) have argued that one of the key (opposing) differences relates to how illness and disease are diagnosed and treated within each system. According to Bell and Koithan, CAM modalities are whole systems that diagnose and treat both acute and chronic conditions and they employ comprehensive diagnostic and therapeutic systems that are guided by a holistic and vitalistic worldview of nature.

The 'vitalism' referred to above is the principle that all living organisms are sustained by a vital force, sometimes viewed as a 'life-force', that is both different from and greater than physical and chemical forces, (Coulter and Willis, 2004). The strong association between CAM and holism is a common theme in the literature on CAM, for example, Pietroni (1987) defined holism as a system of diagnosing and treating the individual within their wider environment (physical and social), using complex interventions and involving the patient in the treatment process. According to Pietroni,

in CAM the whole person is treated, there is a focus on restoring a balance between mind, body and spirit, and the individual patient is conceptualised as having self-healing powers which need to be supported by the treatment.

In contrast to this biopsychosocial approach of CAM, there is the biomedical approach of western or mainstream medicine in which, as argued by Bell and Koithan (2006) diagnosis and treatment focuses on isolated body parts and 'the molecular mechanisms of local symptom expression'; these researchers described the worldview of mainstream medicine as 'reductionistic and materialistic'. Other researchers have also distinguished CAM from mainstream medicine by focusing on the foundations of each system and arguing that fundamental CAM beliefs are diametrically opposed to the tenets of the biomedical model that underpins mainstream medicine. Concepts such as: "high-level wellness"; "the interpretation of mind, body and spirit"; holism; individualism; self-healing; vitalism; the body as a bio-energetic system; and a focus on the natural/ecologic context, all of which are of fundamental importance to most, if not all, CAM modalities, have been contrasted with the biomedical model's strict adherence to western scientific medicine and its key concepts including: a mechanistic model of the body; Cartesian mind-body dualism; and, a reductionist notion of illness that has focused solely on dysfunctional biological processes (Goldstein, 2000a; Micozzi, 1996).

CAM and public health. Jakes et al., (2014) found that 'increasing endeavours' had been made to incorporate CAM into mainstream medicine, but some researchers have been very strongly opposed to the idea of CAM becoming part of mainstream medicine. Colquhoun (2007) criticised universities for offering science degrees in CAM, and CAM modalities such as acupuncture, and argued that there was no evidence base for these healthcare systems and that, in contrast to science, CAM was 'anti-science'. Singh and Ernst (2008) argued that there was no evidence to support claims that CAM treatments were effective; they contended that all the perceived benefits of CAM treatments could be explained by the placebo effect and/or the dynamics of the patient-practitioner process; they dismissed arguments that patient experiences of CAM treatment have been positive and beneficial, and argued that any such experiences were mediated by CAM practitioners acting unethically and dishonestly.

In contrast to these criticisms Long (2013) argued that there was an emerging body of evidence that demonstrated both CAM's effectiveness and its potential to enable, support and enhance people's health and well-being. Long argued that CAM had the potential to enhance healthcare systems and promote personal and community

well-being and health; according to Long, CAM had what he described as, the 'innovative potential' to enhance the public health. Long argued that the holistic orientation of CAM, together with its usual mode of practice (including the high-quality client-practitioner engagement that was a key part of the consultation process) has promoted greater self-awareness and a better understanding of the mind-body connection, which in turn has allowed people to have more control over choices they have made in relation to their own health and well-being. He envisaged that CAM could have an important role in Public Health but noted that such a development would require the mainstream healthcare providers, and the funders of healthcare, to gain more understanding of CAM.

Long (2013) argued that the process of integrating CAM into mainstream medicine had already started, a claim in support of which he cited the work of Rayner, Willis, & Dennis, (2012) who found that integrative medical practitioners were moving towards a public health stance, i.e. they were showing an increased interest in prevention rather than cure and they had recognised the importance of providing patients with good lifestyle advice. Long also argued that making CAM generally available in mainstream health systems, as opposed to it being an 'add-on', would enhance the people's 'critical health literacy' and benefit the public's health.

The Demography of CAM Users

Increases in CAM use in the UK and other countries has been well documented (Jakes et al., 2014; Long, 2013; Posadzki, Watson, Alotaibi, & Ernst, 2013; Nicholl, & Coleman, 2001; Astin, 1998); although, due to the definitional issues as discussed above, estimates of CAM use have varied, those estimates indicate that at least 10%, and as much as 45% of the UK population have used CAM on an annual basis (Posadzki, Watson, Alotaibi, & Ernst, 2013; Thomas et al., 2001; Ernst & White, 2000; Astin, 1998; Eisenberg et al., 1998). Results from a UK wide survey conducted in 2000 indicated that CAM users were spending c£1.6 billion annually (Ernst and White, 2000) and in the USA researchers have reported that the number of consultations with CAM practitioners has exceeded those with conventional medical practitioners (Eisenberg, Kessler, & Foster, 1993). This widespread use of CAM has attracted research interest in the demographics of its users.

Education and income. Studies have identified that CAM users are drawn from higher socioeconomic groups, for example, in 2002 and 2007 NHIS found a positive

relation between the three variables, income, education, and CAM use (Barnes et al., 2004, 2008). Bishop and Lewith (2010) reviewed 110 studies and determined that the relationship between education and CAM use was more consistent than the relationship between income and CAM use, which suggested a factor other than income was responsible for the Education-CAM link, and they proposed that the education-CAM link had arisen because, as people gained more education they also gained more knowledge and awareness of CAM, i.e. these researchers suggested that education empowered people to seek out CAM and predisposed them to become CAM users. A competing explanation was that, because CAM was generally only available at considerable cost its use was prohibitively expensive for the less well-educated, lower socioeconomic groups (Marmot, 2001; Thomas et al., 2001; Carroll, et al., 1993), but Bishop and Lewith (2010) dismissed this argument and argued that individual wealth was not an explanatory factor in CAM use.

Age and gender. Findings from studies that have researched gender differences in CAM have shown conclusively that women are more likely than men to use most CAM therapies; furthermore, although this tendency has been identified in the context of mainstream medicine, it has been shown to be more emphatically true in the CAM context (Bishop & Lewith, 2010; Barnes et al., 2008; Honda & Jacobson, 2005). In contrast, the findings from investigations of a possible relationship between age and CAM use were not conclusive, i.e. some studies suggested CAM users tend to be middle-aged, but others found a linear relationship between age and CAM use (Bishop & Lewith, 2010; Barnes et al., 2008).

Ethnicity and culture. Although the research on the relationship between cultural and ethnic factors, and CAM use, is very limited, some US studies have reported higher usage of CAM from three ethnic groups (Asian, Hispanic and white non-Hispanic); ethnic differences in the choice of therapies suggested that cultural familiarity and beliefs might have influenced modality preferences (Najm, Reinsch, Hoehler, & Tobis, 2003; Arcury, Quandt, Bell, & Vitolins, 2002). Keith et al., (2005) examined the effects of race and ethnicity on CAM use in the USA and concluded that African Americans used CAM less than white Americans.

Bishop and Lewith (2010) drew attention to the lack of research outside of the USA and they completed a UK based study that investigated the relationship between ethnicity and CAM, they were however, unable to draw any firm conclusions due to a

combination of variations in the way CAM was defined, and inconsistencies in the way race and ethnicity were assessed in the papers that they reviewed.

***Demographics of acupuncture studies: summary*.** Virtually all studies that have investigated the demographics of CAM use, irrespective of country and methodology, have indicated that users reflect a particular demographic profile i.e. most CAM users are female (with some indication that they are between the ages of 30 and 40), middle class rather than working class, white, well-educated and live in an urban rather than a rural environment (Davis et al., 2011; Andrews, 2002; Buono et al., 2001; Cherniack, Senzel, & Pan, 2001; Thomas et al., 2001; Astin et al., 2000). Due to a paucity of research little is known about how ethnic origin, culture and low socioeconomic status have influenced CAM use, and how CAM treatment has impacted on the physical and mental health, and well-being of people in these groups, in relation to which Bishop and Lewith argued that more large-scale surveys need to be conducted in the UK and other countries outside the USA.

Why People use CAM

In the UK, the availability of CAM on the NHS is limited and such treatments are not offered in 'most cases' (NHS Choices website accessed 2017) people have therefore needed to make a definite decision to access a CAM service; Campbell and Roland (1996) argued that a decision to consult a CAM practitioner invariably involved a complex mix of social and psychological factors; Van Wersch et al., (2009) concurred and argued that, whether it is mainstream medicine or CAM, people's decisions to access health care has been based on their beliefs, their prior experience and the availability of health care services. Other factors that have been suggested as influencing health care choices include: individual perceptions of personal health needs and the likelihood that those needs would be met by the provision (Kleinman, 1980; Albrecht and Higgins, 1979); health beliefs, personal values, social structures, and the symptoms of illnesses (Mansell et al., 2000; Kleinman, 1978a; Maiman and Becker, 1974); and, personal beliefs, even when they have not had any scientific basis, i.e. lay beliefs about health and illness have been anti-scientific but have still influenced choice (Mechanic,1978).

***Role of chronic illnesses*.** Studies that have investigated the main illnesses or diseases presented by CAM users have provided a clue to one possible motivation for using CAM, i.e. there is evidence that CAM users have been more likely to have

chronic (as opposed to acute) illnesses. For example, Willison et al., (2007) found that chronically ill people used CAM two to five times more often than did non-chronically ill people, and Murray and Shepherd (1993) found that the proportion of CAM users with severe or chronic conditions, such as anxiety, depression, asthma, eczema, hay-fever, or musculoskeletal problems, was higher compared to the proportion of non-CAM users with the same conditions; furthermore, they found that the chronic illnesses in question were more likely to have persisted for a longer time for CAM users, compared to non-CAM users with the same conditions. An understandable conclusion from this finding that the majority of CAM users have suffered from chronic conditions that have not responded to conventional medical treatments, is that CAM users are people who are looking for remedies that they have failed to find in mainstream medicine; Furnham (2007) argued that this was one of two principal reasons that have motivated people's choice for complementary interventions.

Role of consumer choice. The other reason that has motivated people to choose CAM, according Furnham (2007), is the perception by potential CAM users that CAM provides a more natural and effective treatment and one that allows an active role for the patient; Furnham argued that there is some evidence that people have treated medical services like any other product and that CAM users were essentially just consumers who have 'shopped' for a healthcare service in the same way they might have shopped for any other product.

Role of dissatisfaction with mainstream medicine. Researchers have pointed out that in the vast majority of cases the decision to use CAM has not involved a decision to reject mainstream medicine but rather to supplement it with CAM (Nicholl and Coleman, 2001; Astin, 1998; Eisenberg et al., 1993); in fact, studies have found that CAM users have in general used mainstream medicine to a greater extent than those people who have used mainstream medicine alone (Astin et al., 2000; Moore et al., 2000).

Some studies have found that dissatisfaction with mainstream medicine has been a predictor of CAM use (Jakes et al., 2014; ; Cartwright and Torr, 2005; Richardson, 2004; Gould and MacPherson, 2001; Kelner and Wellman, 1997) and other studies have found that CAM-use has been motivated by a variety of reasons including: a lack of confidence in the capacity of mainstream medicine to offer hope of recovery; the perception that mainstream medical treatments have adverse side-effects; poor communication between doctor and patient; and, the quality of the doctor-patient

relationship generally, (Jakes et al., 2014; Paterson and Britten, 1999; Furnham and Kirkcaldy 1996; Vincent and Furnham 1996; Furnham & Smith, 1988). There is however, evidence that dissatisfaction with mainstream medicine has not been a major reason why people have used CAM; Siahpush (1999) reported the results of a multivariate analysis that showed how, after controlling for postmodern values and beliefs, neither dissatisfaction with the medical outcome nor dissatisfaction with the medical encounter in mainstream medicine, were good predictors of attitudes about CAM.

Role of postmodern attitudes. The postmodern hypothesis is that the late modern era saw the emergence of a new value system, that involved ideas related to individual responsibility, authority and consumerism, and that challenged the ability of science, technology and medicine to provide remedies to illnesses and problems of living (Siahpush, 1999). Siahpush argued that postmodern attitudes were a significantly better predictor of CAM use than the predictors discussed above, a view that was supported by O'Callaghan and Jordan (2003).

Siapush argued that postmodernism precipitated an interest in CAM because its philosophies and foundations were congruent with those of postmodernism. Coulter and Willis (2004) concurred and argued that the pressures from postmodern ideas, further fuelled by the emergence of "green" movements that emphasised organic and non-chemical solutions to health problems, impacted on trends in healthcare; they argued that people wanted to have more control over, and wanted to play more active roles in, their own healthcare, which caused a decline in the acceptance of traditional authority figures, most notably doctors. Kelner and Wellman (1997) argued that internet use and widely available encouragement in the media to become more involved in one's own health produced 'smart consumers', i.e. a population that were more proactive and well-informed in health matters.

Role of holistic beliefs. Research has indicated that a concordance between CAM and patients' spiritual and philosophical orientations is another key factor that can predict CAM use (Jakes et al., 2014; Siahpush, 1999; Astin, 1998; Furnham and Smith, 1988). The appetite for holistic life style has been fed by various factors including: a growth in scepticism about science (Siahpush, 1999); more information regarding the value of non-toxic approaches to health care (Bishop et al., 2007; Astin, 1998; Furnham and Smith, 1998); and, a growth in concern for protecting the environment and preventing disease and illness (Kelner and Wellman, 1997; Furnham and Kirkcaldy,

1996; Furnham et al., 1995; Furnham and Forey, 1994). Furnham and Smith, (1988) compared patients using CAM to those using conventional medicine and found that the former group were significantly more likely than the latter group to subscribe strongly to the following beliefs: that the body can heal itself; that treatment should take account of the whole person and not just the symptoms; and, that health is not just the responsibility of the health practitioner.

Astin (1998) found that subscribing to a holistic philosophy of health was predictive of CAM use, and other research has suggested that people who have used CAM have tended to have held beliefs about treatment of illnesses (and illnesses generally) that were well aligned with CAM approaches to health and illness. CAM users have been shown to think about illness using holistic concepts; for example, researchers have found that CAM users were more likely than non-CAM users to hold certain beliefs, related to the importance of self-medication, emotional well-being, and psychological and environmental factors as determinants of health and illness (Jakes et al., 2014; Furnham and Beard, 1995).

Taking an active role in treatment of illnesses and exercising control over personal health have been identified as important elements of holistic approaches to health and there is evidence that CAM users have had self-perceptions that are consistent with these behaviours. For example, Balneaves, Kristjanson and Tataryn (1999) found that nearly all CAM users they interviewed, i.e. 94 per cent of them, wanted to have an active or collaborative role in treatment decision-making, compared to only 56 per cent of non-CAM users. In relation to control over health, studies have shown that CAM users have rated their ability to control their health higher than have non-CAM users, and they have also rated the ability of conventional medical practitioners to improve their health lower than have non-CAM users (Furnham & Kirkaldy, 1996; McGregor & Peay,1996).

Theoretical Models used to Understand and Predict CAM Use

Cameroon and Leventhal (2003) attempted to advance the conceptual understanding of CAM by positing that people are active problem solvers and as such they construct intrinsic ‘common-sense’ models of illness that they then use to assess and evaluate their options for health self-management; similarly, in an earlier study Lewith (1985) argued that CAM users were generally well-informed people in search of solutions to long term problems. Other attempts to achieve the same objective, i.e. to

enhance a conceptual understanding of CAM behaviour, have employed well established theoretical models of health behaviour including: The Health Belief Model (Eisen et al., 1992); The Theory of Reasoned Action (Fishbein & Ajzen, 2011); The Theory of Planned Behaviour (Ajzen, 1991); Leventhal's Self-Regulation Model (Leventhal et al., 2004); and, The Locus of Control Model (Rotter, 1966).

The Health Belief Model (HBM). The HBM identifies health care choices as the consequence of a combination of beliefs related to threats to well-being and the effectiveness of a particular course of action to mitigate those threats (Sharma and Romas, 2012; Becker, 1974; Rosenstock 1966; Hochbaum, 1958). Sirois and Gick (2002) used a version of this model adapted to include the concept of self-efficacy (Bandura, 1997), in an attempt to provide a conceptual understanding of CAM but Jackson (2005) questioned the validity of their findings and argued that the HBM fails to take account of several key factors influencing human behaviour, including social norms and expectations, habits, and institutionalised and non-volitional human behaviour patterns.

The Theory of Planned Behaviour (TRP) & The Theory of Reasoned Action (TRA). The TRA and the TPB models are closely related models that have been very widely researched; TPB is an extension of the TRA in that the TPB model contains all the elements of the TRA plus measures of control belief and perceived behavioural control (Ajzen, 1991). The TPB has been used to predict a wide range of behaviours in health and social psychology; but there is only one published study that has applied it to the prediction of CAM use, i.e. in a study that demonstrated that TPB significantly enhanced the predictive utility of the theory of reasoned action (TRA), Furnham and Lovett (2001) investigated, using the TPB model, the self-reported use of homeopathy. Furnham and Lovett found support for the TPB as a predictor of intentions and use of homeopathy, specifically they found that: attitudes, subjective norms and perceived behavioural control predicted 49% of the variance in intention to use homeopathy; intention predicted 56% of the variance in behaviour (frequency of homeopathy use); and, past behaviour significantly contributed to the prediction of intention and behaviour.

Leventhal's self-regulation model. This model posits that people's self-perception of their illness determines their coping strategies including decisions that they might make to access healthcare systems (Leventhal et al., 2004). The self-perceptions of illness in question consist of beliefs about symptoms, aetiology, illness

duration, consequences, and potential for cure or control (Lau and Hartman, 1983), and beliefs about the treatment itself, including whether it is perceived as necessary, appropriate or potentially harmful (Horne, 1999).

Leventhal's self-regulation model suggests a useful framework for understanding CAM use within the wider context of the illness experience; Bishop et al., (2006) and employed this model in a cross-sectional online study and found that illness beliefs (i.e. beliefs in serious consequences, emotional causation and illness coherence) and treatment beliefs (holistic health beliefs) were predictive of CAM use; furthermore, they also found that different beliefs were associated with the use of different CAM therapies. A weakness with the study by Bishop and colleagues, is that their sample was biased towards those with favourable attitudes towards CAM, i.e. the majority of the respondents had used at least one CAM therapy in the past. A small longitudinal study (N=30) that used Levethal's model found causal beliefs to be most predictive of understanding and adherence to homeopathy (Searle and Murphy, 2000).

The locus of control model. This model, proposed by Rotter (1966), is linked to health beliefs and behaviours and makes the assumption that people have generalised expectancies regarding their control over their environment; i.e. the model suggests that individuals with a high internal locus of control interpret events as resulting from their own behaviour, while those with high external locus of control attribute events to external factors, not under their control, such as luck, chance, fate and the impact of powerful others. While having control over one's health and treatment has been a significant factor in peoples' decisions to use CAM (Kelner and Wellman,1997), findings regarding the more general concept of locus of control are rather mixed. Several studies using Lau's (1982) scale found that users of CAM reported higher self-control over health (Furnam & Bhagrath, 1993) and lower provider control over health (Furnam and Smith, 1988; Furnam and Kirkcaldy, 1996). However, this latter finding may simply reflect a scepticism of mainstream medicine, i.e. it seems that, rather than measuring the belief in health care provider control over health (whether CAM or mainstream medicine), what was actually measured was a belief in the mainstream medicine provider's control over health, a confusion that arose because the provider-control sub-scale referred specifically to 'doctors' rather than health professionals more generally. A later study using multi-dimensional health locus of control scale found no differences in control beliefs between non-users, new users and committed users of CAM. (Sirois and Gick, 2002).

The Changing Conceptualisation of Health to Include Well-Being

In 1946 the World Health Organisation (WHO) defined health as, 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (World Health Organisation, 1946). Although the WHO definition of health refers to well-being, there has been no attempt made to define that term, and arguably the term 'well-being', as well as the term 'health' itself, were presented as rather vague and nebulous concepts; this is evident from the fact that a decade after the WHO definition was proposed Gallie (1956) observed that both terms, 'well-being' and 'health', particularly the latter, were poorly defined, and were 'contested' concepts.

The meaning of 'health'. The WHO's definition of health came into force on 7th April 1948 and has not been amended since that date; it has however been the basis of a great deal of debate and many researchers have attempted to provide a specification of the (positive) factors present, i.e. in contrast to the absence of illness and infirmity. This research has generated various definitions of health including: the ability to reach one's goals (Nordenfelt 1995); adaptiveness (Simmons 1989); having a 'sense of coherence' (Antonovsky 1993); and, 'harmony', 'balance' and 'capacity for activity' (Herzlich, 1993). Some researchers have argued that these definitions are misconceived and have proposed that 'health' should be conceptualised as a complex process of continuous adjustment to the many and varied demands of living, individual potential, and the changing meanings that people have attributed to life (Bircher, 2005; Saracci,1997).

In spite of the efforts that have been made to define health in positive terms, and the fact that the WHO definition itself emphasised that health is more than the absence of disease, Schickler (2005) has observed that, regarding the general usage of the term 'health', it has been taken to mean the absence of disease (mental or physical).

The meaning of 'well-being'. In contrast to the persistence of a perception that health is the 'absence of disease' the concept of 'well-being' has evolved to have quite a different meaning than this; although the WHO's definition of health does not define 'well-being' and arguably uses the term as a synonym for health, over the years thinking has emerged that has promoted well-being and health as different and distinct concepts. From a psychological perspective, well-being has generally been equated with life satisfaction and happiness; it has been regarded as being a condition that enables individuals to achieve their goals, to live in the way they want to live and to feel good

about themselves, both mentally and spiritually, if not physically (Kahneman et al., 1999).

Evidence that health and well-being have been distinguished in the minds of lay people emerged from a phenomenological study completed by Schickler (2005). This research employed a range of methods including multiple interviews with participants that specifically explored the meaning of 'well-being' for lay people; the findings demonstrated that whilst 'well' was used in the context of a 'feeling' (i.e. feeling 'well' is a subjective state that is the opposite of feeling 'ill'), 'well-being' was a term that was used to describe more than just 'wellness', i.e. well-being had connotations of 'higher feelings' which included: enjoyment; energy and vitality; being in control of one's life, including decision making and independence; and, ethical congruity. Well-being was conceptualised as being related to achieving one's potential, i.e. having sufficient energy and vitality to achieve whatever one wanted to achieve, including personal goals, hopes and aspirations, and being in control of making personal decisions that were compatible with personal beliefs, convictions and values.

Schickler (2005) argued that the terms 'health' and 'well-being' have not been used interchangeably, at least by lay people; this position has been summarised by Huppert et al., (2005) who observed that, while well-being could include health, it also went beyond health and included vitality, happiness, creativity and fulfilment. Schickler's argument reflected that of Kleinman (1988), who observed, nearly two decades earlier, that for large numbers of lay people and some professionals, conceptions of health had moved beyond any narrow biomedical definition, and rather than simply subscribing to a reductionist biomedical model of health, people's view of health incorporated social and psychological factors that were not typically included in the treatment goals of orthodox healthcare. Van Wersch et al., (2009) contributed to this discussion and argued that people's conceptualisation of health involved three dimensions: the medical, which is to do with the absence of disease; the psychological, which is to do with well-being; and the social, which is to do with social relationships.

People's relationship to 'health' and 'well-being'. Findings from studies have indicated that people want to participate in and be involved in their healthcare; they desire to have their experiences of health and illness listened to and they make a distinction between health and well-being and place more value on the latter concept. Schickler (2005) argued that consulting a medical practitioner, whether mainstream or CAM, was seen as one means of either restoring or maintaining well-being, with

lifestyle factors such as diet and stress reduction being the most commonly reported well-being factors; furthermore, when consultations produced negative experiences the health practitioners in question were rated as being a source of a loss of well-being. Further evidence that well-being has emerged as a concern distinct from 'health' comes from studies that have shown how for many CAM users, and particularly long-term users, the goal of treatment has been to enhance well-being rather than simply addressing illness, i.e. the evidence suggests that CAM is the natural home for people who are searching for well-being, (Verhoef et al., 2005; Gould and MacPherson, 2001). This explanation for CAM-use is supported by findings that many CAM therapies, e.g. acupuncture, are focused on the maintenance of health and energy rather than the treatment of illness (Van Wersch et al., 2009), and that much of what was identified as well-being, was in a CAM context a form, or some type of, vitality and/or energy (Fulder,1998).

Health, well-being and socioeconomic status (SES). Chamberlain (1997) referred to significant class differences regarding perceptions of health and suggested that higher SES groups have tended to emphasise the importance of 'vitality' and 'well-being' in relation to their health goals, i.e. they have been concerned with well-being as well as (and possibly more than) health. Chamberlin argued that this group have perceived mental and physical aspects of health as an integrated whole; that they have considered health as an interdependent balance of the physical, the emotional, the social and the spiritual. In contrast lower SES groups have tended to subscribe to a more functional and practical, or utilitarian, model of health where the focus has been on simply being able to carry out normal daily activities.

The implication of this distinction between the higher SES groups being concerned with well-being and the interdependent balance of the physical, the emotional, the social and the spiritual, and the lower SES groups being concerned with the purely physical aspects of health, is that the higher SES groups have been more attracted to CAM because their philosophical beliefs are congruent with the underlying CAM philosophy, which has been suggested as an explanation for the observed difference in CAM usage between these groups.

Acupuncture

The National Institute of Health of the United States of America described acupuncture as, "a family of procedures involving stimulation of anatomical locations on the skin by a variety of techniques." ('NIH Consensus Conference. Acupuncture.' 1998); it has been identified as a widely and internationally practiced therapy and one of the most commonly used CAM interventions (Kai-Yin Hsu et al., 2014; Hansard 2000) with trained practitioners and treatment centres, and a therapy that has enjoyed advocacy within the health professions. Furthermore, studies of user attitudes have demonstrated that it has been extremely popular with its client base worldwide, (Paterson & Britten 2004; Gould & Macpherson 2001; Cassidy 1998a, 1998b).

Conditions that can be treated with acupuncture. In 1979 the WHO published a report that officially recognised acupuncture as an acceptable medical practice that was effective in treating various musculoskeletal disorders including: arthritis, back pain, muscle cramp, neck pain and sciatica, anxiety and other emotional related disorders, depression, insomnia, neurosis and nervousness, abdominal pain and other digestive disorders, constipation, diarrhoea and indigestion, cataracts and other eye-ear-nose-throat disorders, gingivitis and tinnitus, and gynaecological disorders.

The WHO report also indicated that acupuncture was effective in treating respiratory disorders including: asthma, bronchitis and common cold, and miscellaneous diseases including: addiction control, chronic fatigue and stress reduction (National Centre for Complementary and Alternative Medicine (NCCAM), 1979). A report from the British Medical Association (2000) made very similar conclusions and, in 2002, the revised WHO report expanded the list of conditions for which Acupuncture was an effective treatment, this report added to what was an already extensive list, a range of pain-related illnesses including: migraine, periarthritis, fibromyalgia, tennis elbow, low back pain, sciatica, sprain, osteoarthritis of knee, gouty arthritis, colic and biliary pain, postoperative pain, dental pain, surgical anaesthesia, epigastric pain, cancer pain, essential hypertension, primary hypotension, induction of labour, leukopenia, malposition of foetus, stroke, non-insulin dependent diabetes mellitus, facial spasm, hepatitis B viral carrier, insomnia, Ménière's disease, polycystic ovary syndrome and pertussis (WHO, 2002).

The evidence-base for acupuncture. The efficacy of Acupuncture is evidence-based with a comprehensive collection of the Cochrane Complementary Medicine field covering the period from 1989 to 2016; this evidence base has undergone expansion

with evidence from RCT's and meta-analyses that have demonstrated clinically significant effects of acupuncture treatment for a range of complaints including: the treatment of pain following oral and gynaecological surgery, (Lao et al., 1994; Christensen et al., 1989); chronic back pain (Furlan et al., 2005; Manheimer et al., 2005); neck pain and various other painful conditions (Vas et al., 2006; White et al., 2004); migraine (Linde et al., 2005); tension headaches (Vickers et al., 2004); and, osteoarthritis of the knee (Witt et al., 2005).

Acupuncture: a collection of different health systems. Acupuncture is an ancient medical practice that originated in China where it was first detailed in circa 200 BCE (Unschuld, 1985). The early texts comprise collections of ideas and methods drawn from different locations and time periods, which continued to grow as China evolved and as acupuncture migrated to Asia and Europe (Macpherson et al., 2008; Birch & Felt, 1999; Unschuld, 1985; Lu & Needham, 1980). According to Birch and Felt (1999) acupuncture's longevity and diverse influences explain why it houses so many varied, and sometimes contradictory ideas and concepts; its rich and diverse history is reflected in how it is currently practiced, i.e. delivered through a collection of different styles that subscribe to different belief systems, theoretical models, and philosophical understandings.

Different styles of acupuncture. Acupuncture is characterised by a collection of heterogeneous conceptual frameworks that guide clinical practice, i.e. the term 'acupuncture' is an umbrella term for a collection of different health care systems, which can be distinguished along several dimensions, including: the particular treatment style adopted, each of which has evolved by emphasising a different theory; how traditional and modern concepts are interpreted and applied; and, how particular sets of clinical skills have been selected, developed and refined.

The dimensions of difference outlined above has translated into differences in the treatment that practitioners from different schools of acupuncture have delivered to their patients. Examples of different treatment procedures include: divergent approaches to the selection of acupuncture treatment points, ranging from general body points, to specific scalp points to microsystem points such as ear or hand acupuncture; different needling techniques ranging from variations in how many needles are used and for how long to diverse types of needling stimulation such as electro-stimulation, micro-current, laser and ion pumping cords; use of adjunctive techniques such as moxibustion, injection of points, and the application of colours and sounds; differences in the number

and frequency of treatments deemed necessary, ranging from a single treatment to multiple treatments over a period of weeks or months or longer, (MacPherson et al., 2008).

To some extent the availability and popularity of different schools of acupuncture varies from country to country, in the UK the widely known and available styles of acupuncture include: Traditional Chinese Medicine Acupuncture (TCMA); Five Element Acupuncture; Medical Acupuncture; Japanese Acupuncture; Toyo Hari; Korean Hand Acupuncture; Auriculotherapy and, Trigger point Acupuncture (Macpherson et al., 2008; Servan-Schreiber, 2004). Taylor (2004b) has drawn attention to how some 'styles' of acupuncture, which have emerged from purely western interpretations of the traditional practices, have been passed off as 'traditional', i.e. based on Traditional Chinese Medicine, when they have in fact been based on fresh interpretations.

Researchers have cautioned against the marked tendency to not report the particular style of acupuncture being investigated in studies (Birch, 1997), and argued that styles differ and no one school is representative of all the other schools, (Birch & Felt 1999; MacPherson & Kaptchuck 1997); the present study took account of these arguments and investigated one specific school of acupuncture, TCMA, a popular style in which the diagnosis is based on the understanding of disease of traditional Chinese medicine, (Kaptchuk, 1983, O'Connor & Bensky 1981).

Traditional Chinese Medicine Acupuncture (TCMA)

TCMA originated in East Asia and is a part of a holistic health system that is estimated to be about 2000 years old; in common with many styles of acupuncture, in TCMA, the patient, the practitioner and the treatment are conceptualised as being an integral unit or system in which an interactive process of diagnosis and treatment dynamically develops as part of a feedback loop (MacPherson et al., 2008). TCMA regards pain and illness, whether physical or mental, as indicating that the body is out of balance; as every bodily function is considered to be connected and interdependent, a lack of balance can have diverse origins, including human emotions, which are recognised within TCMA as having a role in illness and disease.

Bresler (1975) explained that a fundamental tenet of TCMA is that illness and pain occur when the body's vital energy, known as 'Qi', is unable to flow freely; in this style of acupuncture the body is considered to have numerous internal pathways i.e.

energy meridians, through which Qi flows, and these meridians can become obstructed in a way analogous a trapped nerve or blocked artery, such obstructions can be precipitated by many factors, including: emotional disturbance, physical stress, poor nutrition, infection, physical or psychological injury. Bresler (1975) argued that the key goal of TCMA treatment is to remove the obstructions to the free flow of Qi energy and restore the body's equilibrium.

TCMA: procedure and characteristics. The acupuncturist in TCMA needs to understand a patient holistically which involves taking a comprehensive personal and medical history in order to generate a profile that includes lifestyle as well as physical, psychological and emotional experiences. This process typically involves recording details of a range of patient variables, including: current medical complaints and symptoms, diet, digestive system, excretions, sleeping patterns and emotional states. The practitioner also assesses subtle factors such as pulse quality, tongue colouration, general complexion and body odour as well as muscular tension and pain, which will usually involve palpation, (Maciocia, 1998).

All of the collected information is amalgamated to produce a diagnosis, which is then conveyed to the patient in traditional terms along with a treatment plan; the latter will normally include a therapeutic intervention, e.g. needling, as well as advice, based on Traditional Chinese Medicine theory, regarding changes in behaviour, this typically will include recommendations on diet and lifestyle changes. In contrast to the typical mainstream medical approach that focuses entirely on the presenting complaint or symptoms, the TCMA practitioner's diagnosis and decision to use a particular treatment is a function of the patients' unique constitution, lifestyle, emotional state and presenting complaints. Importantly therefore, patients with similar conditions, as diagnosed by western medical practitioners, will not necessarily be treated in the same way by a TCMA practitioner (Maciocoia, 1998, 2000).

The goal of treatment in TCMA is to restore the body's balance and trigger its natural healing response, which is achieved by re-establishing the free flow of Qi; the practitioner uses ultra-fine needles that are inserted into defined and specific acupuncture points the effect of which is to enhance the natural healing process (Thomas et al., 2005). The selection of needling points is determined by the patient's report of pain and/or other signs and symptoms of their presenting complaint(s). The needles are inserted and manipulated with the objective of creating in the patient a particular sensation, known as 'de qi', which is considered to be the result of the Qi

flowing freely, i.e. unblocked. When 'de qi' is successfully activated patients typically experience multiple sensations at and around the needling site, which might include: distension, numbness, heaviness, travelling sensation, aching, soreness and (very occasionally) pain, (Langevin et al., 2001; Maciocoia, 1998/2000). The practitioner is also able to detect de qi, for example, when it is activated the force needed to remove the needle increases, which is an effect that has been described as analogous to a fish that has bitten onto the bait, (Lundeberg, 2013).

TCMA: the non-needling aspects of treatment. In addition to needling acupuncture points, a traditional TCMA treatment might involve other Chinese medicine techniques including: moxibustion, which is the application of indirect heat using moxa, i.e. therapeutic herbs, and/or heat lamps to warm and relax muscles and energy meridians; cupping, which is the application of glass cups with a vacuum seal placed on the skin to stimulate blood flow and move 'stuck' Qi; guasha, which is vigorous rubbing of the skin to increase blood flow and move stuck Qi; electro-acupuncture, which involves a very low frequency electrical current (1Hz) being applied to the acupuncture needle to increase blood flow, relax muscle tissue and move stuck Qi; the administration of herbal medicines; and, Chinese therapeutic massage, i.e. 'Tuina', which relieves muscle tension, stimulates acupressure points, opens energy meridians and stimulates the flow of Qi (MacPherson & Kaptchuk 1997).

TCMA: how it works. As explained by Langevin et al., (2001) and Maciocoia (1998, 2000) a fundamental principle of TCMA, and acupuncture generally, is the existence of Qi, a vital energy within the body. TCMA works by balancing the flow of Qi and practitioners measure it in order to monitor the efficacy of their treatments. Measuring the Qi is achieved by checking the patients pulse quality (a procedure different to the western pulse taking procedure), which serves clinically as a surrogate marker of Qi, i.e. measuring quality of pulse does not provide a direct measure of Qi. Practitioners compare pulse quality before and after needling (or other treatment) to monitor and assess whether imbalances in Qi flow have been corrected. However, in contrast to measurements made by western medical practitioners where the biomedical model allows a precise measurement, in TCMA measurement is guided by a more experiential model, i.e. the nature of Qi is elusive, and its measurement relies on the practitioners' knowledge and understanding of the nature of Qi itself.

Scientific Evidence for the Effectiveness of Acupuncture

Although acupuncture is an umbrella term covering a variety of different approaches to treatment, all of which are significantly different (Birch, 1997), with no one school being representative of all the others, (Birch & Felt 1999; MacPherson & Kaptchuck 1997), there are nevertheless concepts and ideas that are common to all the main schools of acupuncture (Jakes et al., 2014), including: the concept of a type of energy known as Qi, (discussed above); the idea that Qi flows through channels, i.e. 'meridians', in the body; that imbalances in Qi are the cause of illnesses; and, that techniques such as needling can resolve those illnesses by restoring balance to the Qi. Some authors have focused on these ideas in attempts to re-interpret acupuncture in terms of the evidence based medical paradigm which has dominated mainstream medicine for nearly three decades (Godwin, 2014; Filshie & Cummings 1999), the results of these efforts to explain acupuncture in a biomedical framework are mixed.

Evidence needed to explain the effects of acupuncture in terms of the biomedical model of mainstream medicine has accumulated over the years and includes: findings that acupoints and meridians could be identified on the basis of their bioelectrical properties, e.g. electro-dermal identification of acupoints, (Becker et al., 1976, Colbert et al., 2004), although this research has been criticised for failing to control for confounding variables and for methodological problems related to instrumentation and a lack of replicability of the reported studies (Martinsen et al., 2001, McCarroll and Rowley 1979); findings of a correspondence between classically defined acupuncture and infrared images produced by thermal radiation (Ovechkin et al., 2001, Lo 2002, Schlebusch et al., 2005); and, findings that needle insertion at acupuncture points produces increased levels of endogenous opioids in human blood and cerebrospinal fluid (Benedetti et al., 2005), although these researchers have not offered an explanation of how a signal is propagated by a needle inserted in an acupuncture point.

Some evidence has also emerged from animal studies, e.g. studies in hypertensive animals has demonstrated that electro-acupuncture induces increases in peri-arteriolar Nitric Oxide and Nitric Oxide Synthetic enzyme; Nitric Oxide is a multi-functional molecule that acts locally to regulate cellular processes, it has been identified as a modulator of blood vessels and Kim et al., 2006 found that increases in Nitric Oxide during electro-acupuncture are correlated with mean decreases in arterial pressure.

Researchers have attempted, with some success, to explain the effects of acupuncture in a biomedical context and they have argued that it works as a result of neural mediation, i.e. that acupuncture points are sites on the body where sensory nerve endings can easily be activated by needling (Chiang et al., 1973, Heine 1998, Uchida et al., 2000, Li et al., 2004). Others have argued that acupuncture's established pain modulating capabilities are the consequence of needling causing the synthesis and release of endogenous substances, such as encephalin, endorphin, dynorphin, (Han 2003, Pomeranz 2001, White 2006), and this theory has received some support from brain imaging studies (Napadow et al., 2006a); using medical imaging techniques, Napadow and colleagues, identified acupuncture as stimulating secretions of endorphins in the brain, which produces pain modulating effects, i.e. endorphins have effects similar to morphine and heroine in terms of pain modulation. Ulett et al., (1998) have also produced some evidence suggesting that pain reduction following acupuncture might be the consequence of brain chemicals and they have demonstrated that acupuncture produces secretions of brain chemicals that block the experience of pain beyond any placebo effect.

Additional explanations arising from studies that have attempted to explain acupuncture in the context of a biomedical model include: MRI studies that have demonstrated that correlations exist between acupuncture and activity in the emotional brain (Hui et al., 2000, Pariente et al., 2005), and the idea that acupuncture promotes coherence in cardiac rhythm, which emerged from findings that acupuncture had a direct effect on both branches of the autonomic nervous system, i.e. the sympathetic and parasympathetic systems. Specifically, regarding the latter point, acupuncture has been shown to be correlated with increases in parasympathetic activity and decreases in sympathetic activity. Research has also suggested that acupuncture's effects are the result of collagen-based connective tissue networks, a finding that resulted from studies that used ultrasound technology and demonstrated a correlation between acupuncture meridians and connective tissue planes. Studies have found that, as an alternative to neural pathways, networks of collagen-linked fibers functioning as flexible liquid crystals, can transmit bio-information throughout the organism to produce the effects observed from acupuncture. (Langevin and Yandow 2002, Langevin et al., 2004, Ahn et al., 2005, Ho and Knight 1998, Oschman 2003). These various explanations are not necessarily mutually exclusive, for example, Ansel et al., (1996), found that acupuncture results in mechanical or electrical perturbations that trigger an interaction

between neural and connective tissue, which in turn produces the observed effects of acupuncture.

Godwin (2014) argued that the key to establishing acupuncture as a treatment equal with others in mainstream medicine is for the traditional system of acupuncture anatomy to be mapped comprehensively onto a biomedical system; he argued that the most promising tool for identifying how acupuncture works within a biomedical context is neuroimaging; in support of his argument he identified evidence, that has emerged from neuroimaging, for at least three important outcomes that acupuncture is thought to mediate, i.e. that acupuncture can modulate complex physiologic processes; that acupuncture points have specific effects; and, that measurably different effects can be produced by different manipulations and methods of stimulation.

Framing acupuncture in a biomedical model: the risk of losing its essence.

The findings from mainstream medical science-based research has not convinced all practitioners that it is potentially fruitful to continue with this work; many researchers have expressed the view that attempts to frame acupuncture in a biomedical model are misconceived because such efforts cannot take account of important aspects of acupuncture without which the essence of the system is lost (Lewith et al., 2002). A specific example of the difficulty of providing a biomedical explanation of acupuncture relates to the measurement of the sensory components of 'de qi', a sensation that is central to the success of TCMA and acupuncture generally; Lundeberg (2013) has explained how attempts to study this key sensation in a biomedical context are difficult because of its subjective nature and the fact it is influenced by so many factors including the unique constitution of the individual patient.

TCMA: Researching a Complex Healthcare System

Boon et al., (2007) explained that the term 'complex healthcare systems' refers to healthcare systems that involve complex interventions to combat disease and promote health and complex and entangled interrelationships between the active components of those interventions and the healthcare system itself. Boon and colleagues identified CAM as a complex healthcare system and argued that attempts to investigate it using the single component interventions that have been used in the research within the biomedical model have had 'significant limitations', and they have argued that multiple component interventions based on a broader theoretical perspective are required. Boon and colleagues defined a complex healthcare system as a 'complex intervention to

improve or enhance health and well-being as well as to prevent disease', a definition that was adopted in the present study.

It has been argued that acupuncture generally, i.e. all schools and approaches, is amongst the most popular of all the CAM modalities (Patterson and Britten, 2004) and that it is recognised as a complex healthcare system, even when it is narrowly defined by needling alone (Niestra-Ortiz, 2014). In relation to the practice of defining acupuncture by needling alone it is important to note that acupuncture involves a dynamic process far broader than simply inserting needles and that in researching acupuncture there is an important distinction that must be made between researching the efficacy of needling and researching the efficacy of acupuncture; furthermore, it has been argued that as opposed to isolating the treatment effect, restricting acupuncture to needling alone might actively interfere with it. (MacPherson et al., 2006b; Paterson & Dieppe, 2005; Paterson & Britten 2004).

TCMA, the school of acupuncture that was the focus of the present study, has a complexity that arises from the many interacting components that are involved in the diagnosis and treatment process, which includes both needling and non-needling components. Component variables of needling in TCMA include: synthesising diagnostic judgements with other patient information to determine and guide the treatment plan; judgements about the number of needles required, their insertion points, the depth and the duration of insertion; and, the monitoring of both the needle sensation of 'de qi' and the stimulation method used for directing Qi in a specific way (Bovey, 2006). The non-needling component variables, typically include: palpation employed as a diagnostic tool to enhance clinical judgements; advice and guidance provided to the patient to facilitate their understanding of their condition within the theory of TCMA; and, managing the patient's active involvement in the treatment process to encourage appropriate lifestyle changes (MacPherson et al., 2006). TCMA is a 'complex intervention' with its own research needs, most notably, all the needling and non-needling components referred to above, as well as the specific theories, concepts and traditional explanations of TCMA need to be incorporated within the TCMA paradigm to be researched (Verhoef et al., 2005; Medical Research Council, 2000; Acupuncture 1998); assessing TCMA presents a number of methodological problems the most significant of which are discussed below.

Methodological Challenges in Acupuncture Research

West (1997) argued that, in common with other complete healthcare systems, TCMA is a self-organising system that involves a complex interaction of its numerous component parts, the result of which typically includes the emergence of new properties that cannot be identified as derivatives of the individual interacting components; other researchers have argued that, in common with most (if not all) CAM modalities, the effects of a whole TCMA intervention is greater than the sum of its parts, i.e. the contribution of the component parts of a TCMA intervention are interactive not additive (Verhoef et al., 2004; Ritenbaugh et al., 2003; Bell et al., 2002).

Acupuncture and mainstream medicine: different paradigms. The term 'paradigm' refers to a particular model or world view and the concept was introduced by the physicist and philosopher of science Thomas Kuhn (1970) who described scientific evolution as involving one paradigm being replaced by another, a process known as 'paradigm shift'; paradigm shift has been described as a transition from one way of viewing the world to another way of viewing it (Vickers, 1996a). The debate regarding which is the best methodological approach for evaluating CAM, which has been described by Godwin (2014) as essential if acupuncture is to establish itself as a full partner next to mainstream medicine, is one that has arisen between practitioners who have subscribed to one or other of two particular paradigms, i.e. the biomedical paradigm of mainstream medicine and the biopsychosocial paradigm of CAM. The latter is characterised by a holistic explanation of health and illness and key ideas or concepts, including: "high-level wellness"; "the interpretation of mind, body and spirit"; holism; individualism; self-healing; vitalism; the body as a bio-energetic system; and a focus on the natural/ecologic context, all of which have been identified as being of fundamental importance to most, if not all, CAM modalities, (Goldstein, 2000a; Micozzi,1996). While the biomedical paradigm is characterised by a strict adherence to western scientific medicine and certain key beliefs including, a mechanistic model of the body; a Cartesian mind-body dualism; and, a reductionist notion of illness that focuses on dysfunctional biological processes; it has been described as 'reductionistic and materialistic', (Bell and Koithan, 2006).

There has been a common perception that these two paradigms are very significantly different and sometimes are in direct conflict, and researchers have argued that research methods developed in one paradigm are not transferable to the other and that practitioners working within each paradigm have been unable to look outside to

understand the other paradigm (Patterson & Dieppe, 2005; Kaptchuk, 1996). These conflicting beliefs have sometimes resulted in uncompromising statements defending and attacking the two paradigms. For example, Heron and Reason (1984) argued that the gold standard methodology of the orthodox medical paradigm, i.e. randomised controlled trials, is a source of alienation because it has created a separation between patients and events in their bodies and has denied patients an involvement in decisions about their treatment. In contrast, Godwin, (2014), who has been a strong advocate of the evidence based biomedical paradigm, has argued that unless acupuncture can be validated by the biomedical model it will never be fully integrated into mainstream medicine; he has argued that acupuncture's holistic paradigm has failed, that the profession of CAM needs to embrace the biomedical paradigm of mainstream medicine, and that the required paradigm shift can best be achieved through a combination of systematic reviews, meta analyses and RCT's.

Resolving potential sources of bias in RCTs. Paterson and Dieppe (2005) argued that the double blind randomised controlled trial (RCT), that has been widely used in mainstream medicine as a powerful and productive tool in the testing of new drugs, has migrated to the evaluation of complex interventions including acupuncture, and has resulted in the research into acupuncture's clinical effects being based largely on the biomedical drug model of a placebo-controlled RCT. However, this has not proved to be a welcome development and many CAM and acupuncture researchers have questioned the validity of this methodological approach; they have pointed out how several well-conducted and large RCT's of acupuncture have, at best, produced inconclusive findings, and, at worst, contradictory findings; they have generated challenges but have not provided any remedies (Birch et al., 2004).

The problems associated with using RCT's in evaluating acupuncture were examined by Paterson and Dieppe (2005), who argued that, unlike simple interventions such as drug trials, in which RCT's have proven so useful, acupuncture is a complex intervention that is not methodologically congruent with the RCT model. They explored this apparent lack of congruence and identified how, in the context of acupuncture, the basic assumptions that underlie RCT's are invalid. The basic assumptions they examined were: that a diagnosis can be made before the trial begins; that incidental factors such as patient-practitioner relationship do not contribute significantly to therapeutic outcomes; and, that actions that contribute to therapeutic outcomes are additive. They described how in acupuncture, diagnosis was ongoing,

treatment evolved with it and there was no equivalent to the western biomedical diagnosis that determined treatment in advance; factors such as discussions between patient and practitioner were considered central to the effectiveness of the treatment process in acupuncture and were not the 'incidental' factors that they were considered to be in mainstream medicine; and, in line with the holistic foundation of all CAM modalities (i.e. that the whole is greater than the sum of the parts) the various actions that contributed to therapeutic outcomes were not simply additive. On the basis of these false assumptions Paterson and Dieppe (2005) concluded that the use of RCTs alone, in studies to evaluate acupuncture, would in all probability fail to detect real effects when those effects exist, i.e. they argued that RCT trials of Acupuncture were likely to produce 'false negatives'.

Researchers have argued that CAM modalities like acupuncture are complex interventions that require a different approach to evaluation than the traditional RCT (Boon et al., 2007; Bell and Koithan, 2006) an issue that has been addressed by the Medical Research Council (MRC), i.e. the MRC 2008 and 2014 guidance documents suggested that the evaluation of complex interventions requires a rigorous outcome evaluation, to determine if the intervention works, together with a process evaluation, to determine how it works (Moore et al., 2015; Craig et al., 2008). In line with this MRC guidance the present study involved both outcome and process evaluations; the process evaluation element of the present study was important because it promoted an understanding of how TCMA worked in practice, and therefore made a potential contribution to an evidence base that can inform policy and practice (Moore et al., 2015).

The problems of finding a placebo in RCT studies of acupuncture. A major methodological problem with attempts that have been made to assess acupuncture using a placebo-controlled double blind RCT has been the identification of a suitable placebo. A placebo needs to be indistinguishable from the real intervention, e.g. it must appear identical to and create the same sensations as the real intervention but have no therapeutic or physiological effect. In acupuncture, however, because a placebo necessarily involves something touching the skin, there is a major problem arising from the fact that touch involves physiological stimulation, which excites diffuse noxious inhibitory control (Bing et al., 1991) and might also have clinical effects on pain (Lewith and Vincent, 1995).

The most common placebo control that was used in studies, and found to be generally acceptable to patients, was 'sham acupuncture', this procedure initially involved inserting needles at incorrect and theoretically irrelevant sites that were near to the classical locations, with the depth of insertion and the stimulation being the same as the real treatment, i.e. it was only the location of the point that differed. This type of sham acupuncture was used in many studies, but evidence suggested that it is was not a valid placebo, i.e. it was argued that analgesic effects resulted from needling at non-classical locations which violated the conditions required of a placebo (Vincent and Richardson,1986; Lewith and Machin, 1983; Vincent,1993). This failing was addressed with an improved procedure that involved the use of 'placebo needles' which were applied to the actual locations without penetrating the skin and were indistinguishable from the real active needles (Takakura and Yajima, 2008, 2011; Park, et al., 1999). However, these technical advances in the sham acupuncture needles did not satisfy all the objections raised regarding the validity of sham acupuncture in double blinding. The fundamental error that bedevilled almost all experimental and clinical controlled trials of acupuncture that employed the sham acupuncture control condition, was that it only provided information about the most effective sites of needling, and not information about the specific effects of acupuncture.

Inappropriate placebo control has been the most serious methodological problem in clinical RCT's of acupuncture, i.e. having no appropriate placebo control has completely invalidated many (if not all) studies, and it is a problem that has undermined findings from experimental and clinical controlled trials of acupuncture (Birch et al., 2002; Vickers AJ, 2002); as yet a control condition with negligible or non-existent physiological effects has not been identified.

The problems of 'blinding' in RCT studies of acupuncture. The blinding process in RCT's is itself a challenge in terms of RCT studies of acupuncture; 'blinding' refers to the process of concealing the treatment and the control assignments from either or both the researcher and the participants/patients. In a 'single blind' design only one or other party, i.e. researcher or patients, is 'blinded', and in the 'double blind' both the researcher and the patients are 'blinded'; the double blind RCT is the 'gold standard' design methodology that theoretically reduces sources of bias from both the researcher and the patients. However, researchers have questioned whether double blinding is possible in acupuncture on the basis that a competent

acupuncturist would be able to detect the difference between any sham acupuncture and active acupuncture.

Vase et al., (2015), investigated this issue in a randomised study involving 67 patients with acute pain; they explored whether the acupuncturists (n=6) and the patients could distinguish sham acupuncture (which Vase and colleagues labelled placebo acupuncture) from real or active acupuncture. They found that the acupuncturists could distinguish the placebo from the active acupuncture in over 80% of the treatments and patients could distinguish them in over 60% of the treatments, they subsequently concluded that full double blinding was not achievable in acupuncture, and in particular, practitioner blinding was challenging.

Are RCT's inconsistent with the theoretical foundation of acupuncture? The problems of employing placebo controlled RCT's in acupuncture research has been detailed by a number of researchers: Walach (2011) argued that the components of acupuncture treatment that produce the treatment outcome are not separable, discreet components as they are assumed to be in mainstream medicine but rather, they are potent and essential parts of the treatment; Stoney et al., (2009) argued that the supposed discreet, inert factors conceptualised in mainstream medicine have the potential to influence physiological arousal and can cause changes in endorphin levels; Black (1996) argued that in any CAM intervention, RCT's are likely to undermine the placebo elements, such as psychosocial effects or other non-specific effects, causing those non-specific treatment effects to be lost with the consequence that clinical trials would inevitably reflect only the minimum level of benefit that could be expected from the modality being investigated; Sharma (1992) argued that RCT's exclude aspects of the patients' lives such as: emotional state, social situation, attitude and state of mind, all of which are important in the healing process of CAM modalities, including acupuncture; and, Kaptchuk (1996), questioned the validity of key assumptions, implicit in the use of RCT, e.g. that acupuncture could be conceptualised as a simple or single component intervention.

RCT's: Problems of Validity and the Need for an Alternative Methodology

An important methodological problem with employing RCT's to assess acupuncture (and other CAM modalities) relates to the scientific concepts of validity, which, Khorsan and Crawford (2014) have explained, is the extent to which the findings and conclusions of a study are likely to be true and bias-free. Khorsan and Crawford

explained that validity is made up of three sub-types of validity, i.e. internal validity, external validity and model validity.

Internal validity concerns whether or not the findings and conclusions of a study are valid for the study population, i.e. the people recruited for the study; if a cause–effect relationship has been demonstrated as existing for the study population then internal validity is high and vice versa. Internal validity is a prerequisite for external validity which concerns the generalisability of the study, i.e. external validity is about the degree to which any observed effects in the study would be seen in general terms outside of the study and it indicates the degree to which the results from studies of acupuncture are representative of actual practice; high external validity indicates the results from studies are representative of actual practice and low external validity indicates the results are not representative of actual practice. Vickers (1995c) argued that any study attempting to assess effectiveness must have good external validity, which emphasises the importance of evaluating interventions under 'normal' treatment conditions, i.e. a clinic setting, an issue that was also identified by Fitter and Thomas (1997) who argued that it was important for practitioners to give individualised patient treatments.

Khorsam and Crawford (2014) argued that in healthcare research more attention was given to internal validity than was given to external validity, which in their view was misconceived because, whereas external validity is concerned with the practical application and usefulness of an intervention to the general population, internal validity is a much narrower concept that is only concerned with an intervention's efficacy in an ideal situation.

***The importance of model validity in acupuncture studies*.** Khorsam and Crawford (2014) explained that model validity is a subset of external validity that is particularly important in the context of researching CAM interventions; it is a measure of how adequately the methodology has addressed the unique healing theory and therapeutic context of the intervention. Verhoef et al., (2005) argued that model validity indicates whether or not the correct model of theory and practice has been tested and they noted that RCT's often entail effectively testing an entirely different model of theory and practice. The problem has been described with reference to Popper's model of the scientific method, i.e. the concept that any scientific experiment is entirely dependent on the initial theoretical framework or model, but experiments designed to evaluate acupuncture have had significant difficulties formulating, or have

ignored, a valid model of 'acupuncture' based on a clearly articulated theoretical framework.

Making research on acupuncture relevant and meaningful. Dale (1997) argued that acupuncture has a continually evolving set of practices and well-structured frameworks; it is a highly heterogeneous health care approach with a large number of different styles and practitioners frequently practice more than one of these styles, but reviews of acupuncture have failed to recognise the diversity of styles within the studies that they have examined, and consequently the conclusions that those studies have drawn cannot be viewed as meaningful. Other researchers have argued that for research to be meaningful it needs to recognise the rich diversity that characterises acupuncture and have clarity about the approach that is being prioritised and evaluated (Allen et al., 2006, Wayne et al., 2005). Birch (1997) argued that clinical trials need to identify which specific elements of the theoretical foundations of Chinese Medicine are being used to guide the choice of any particular treatment protocol; Schnyer & Allen (2005), concurred with this view and argued that, for meaningful conclusions to be drawn from clinical trials, the selected treatment protocol must be consistent with the design and methods of the study as well as the specific objectives and research questions, a requirement they described as 'challenging' because of the broad diversity of treatment options available. Whole systems research has emerged in response to the problems outlined above in relation to investigating acupuncture with traditional tools such as RCTs.

Whole Systems Research (WSR): A 'Holistic' Methodology for Acupuncture Research

A 'whole medical system' has been defined as 'a complete system of theory and practice that has evolved independently from or paralleled to (allopathic) conventional medicine' (NCCAM, 2005). Many CAM modalities, including acupuncture, have been recognised as whole medical systems (Niestra-Ortiz, 2014; Verhoef et al., 2005), which has important implications in the context of how are evaluated, i.e. researchers have argued that the components of whole systems need to be conceptualised as dynamic networks and that the use of reductionist strategies, which focus on evaluating 'active' individual ingredients, are inappropriate (Boon et al., 2007; Bell and Koithan, 2006). Boon and colleagues argued that attempts to evaluate whole medical systems like acupuncture using single methods alone, such as RCTs, could not capture the real

meaning and the process and the outcomes of the intervention; they argued that an appropriate alternative approach was triangulation, an approach that combines qualitative and quantitative research methods.

Boon et al., (2006) and Carter (2003) have argued that a comprehensive research design, capable of addressing all the complexities of a whole system that is patient-centred and sensitive to the philosophical assumptions underlying it, can be realised by combining qualitative and quantitative methods, and Broom et al., (2004) argued that the evaluation of complex systems is most effectively achieved using a multi-method approach involving the triangulation of information sources. The possible information sources that can be employed to assess acupuncture include: single case designs, qualitative approaches, outcome assessment, clinical audit, and observational studies, (Melchart et al., 1997; Black 1996; Reilly and Taylor, 1993).

Whole Systems Research (WSR) for evaluating acupuncture. WSR is a methodology that emerged in response to the growing acceptance regarding the ineffectiveness of using quantitative methods alone, such as RCTs, to research whole medical systems like acupuncture (Ritenbaugh, et. al., 2010). WSR is a research framework that is explicitly non-reductionist and, in contrast to more conventional research methodologies such as RCT's, it is not restricted to evaluating single agent or uni-dimensional effects it combines qualitative and quantitative methods which allows for the assessment and evaluation of system level phenomena (Rittenbaugh et al., 2003) and it takes account of the holistic philosophy that is the foundation of many whole healthcare systems, e.g. the principle that the effect of the whole is greater than the sum of its individual component parts.

Taking account of 'outcome' and 'process' dimensions of acupuncture trials. WSR encompasses the specific and the non-specific treatment effects of an intervention such as acupuncture and it provides a powerful tool for both understanding and maximising the complete effects of such treatments; one of the key strengths of WSR is that it enables a whole healthcare system like TCMA to be assessed in the context of the unique explanatory model upon which it is based, which in turn provides an evaluation of that explanatory model (Verhoef et al., 2006; Verhoef et al., 2005; Cassidy, 1998a/1998b). WSR has the explicit goal of including both 'outcome' and 'process' dimensions of an internally consistent approach to treatment: outcome dimensions refer to change that persists beyond the consultation, such as reduced pain, or changes in energy levels, and process dimensions refer to all aspects of patient care, such as, being

recognised, supported, touched and given empathy. Although outcome and process dimensions are distinct they are linked by complex and mutually reinforcing influences that operate synergistically to create the patient experience.

Verhoef and colleagues explained that, in addition to the 'processes' and the 'outcomes' of the complex interventions being analysed, WSR takes account of how interventions like TCMA have a qualitatively different approach to diagnosis and treatment, and the healing process, which is conceptualised as involving a combination of patient and practitioner knowledge and skills. They proposed a particular WSR approach, which they argued takes full account of outcomes, processes and their complex interactions; their model comprises five outcome categories as follows: i. physical outcomes, which includes aspects of physical well-being such as biological markers, dimensions of physical functioning, and physical symptoms such as pain; ii. psychological outcomes, which includes moods, motivations, and perceptions of health and healing such as expectations, control and resilience; iii. social outcomes, which includes aspects of relationships and social support structures, utilisation of health care services and daily role functioning; iv. spiritual outcomes, which includes feelings of relaxation, hope and empowerment; and, v. a holistic outcomes category that incorporates the first four categories. According to Verhoef and colleagues the total patient experience is the result of these outcome categories interacting synergistically with process factors, including the intervention context and individual factors that are integral to the healing process.

WSR: appropriate Patient Reported Outcome Measures (PROMs). Patrick et al., (2008) defined a Patient Reported Outcome Measure (PROM) as, "a report coming directly from patients about how they feel or function in relation to a health condition and its therapy without interpretation by healthcare professionals or anyone else." PROMs assist clinicians to provide better and more patient-centred care (Black, 2013).

In broad terms PROMs are tools used to measure treatment effects; they can be either generic or problem-specific and they are typically in the form of questionnaires and/or checklists. They can be divided into two broad types: objective outcome measures, which measure 'objective' variables such as blood pressure, hormone levels, and degree of limb movement; and, subjective outcome measures, which measure 'subjective' variables such as self-perceived changes in physical, mental and/or emotional states; some also make subjective measures of social functioning levels, for example, the well validated SF-36 (Brazier et al., 1992) where patients respond to pre-defined questions about treatment outcome by scoring in

terms of severity, as opposed to other tools where the patients prioritise the issues that are important to them.

The subjective PROMs are more relevant for WSR, (Paterson, 1996; Ruta et al., 1994), and the individualised versions (Paterson & Britten, 2003; Paterson 1996; Ruta et al., 1994), are particularly relevant in the context of acupuncture; this is because they are patient-generated measures, i.e. they allow the patient to determine the focus of attention as opposed to that focus being defined as the outcomes for any particular diagnosis or condition. The patients first identify the significant problems, and the ways in which those problems affect their lives, they then score these items for severity. This approach involving patient participation and individualised outcomes as indicators of treatment success has high model validity and fits within a whole systems philosophy.

There are several PROMs that might appear, prima facia, to be appropriate for evaluating TCMA many of these alternatives can be excluded for various reasons. Some are cumbersome because of their complexity and the length of time required to complete them, this category would include the Schedule for the Evaluation of Individual Quality of Life (SEIQoL) (Hickey et al., 1999) and the Patient-Generated Index (PGI) (Ruta et al., 1994); others are disease specific, which includes The Rotar Cuff Quality of Life (RC-QoL) (Patrick et al., 2008) and the MACTAR, a measure of functional impairment in rheumatoid arthritis (Tugwell et al., 1987); and some are only partly patient-centred in that they have individualised sections within a pre-set questionnaire, such as that developed for people with chronic lung disease (Guyatt et al., 1987).

MYMOP: the preferred outcome measure for acupuncture trials. MYMOP is a patient-generated outcome instrument capable of measuring effects from a wide range of health care interventions and, of growing importance to patients, it is appropriate for use in CAM (Hermann, K., Kraus, K., Herrmann, K., & Joos, S. 2014); of all the PROMs available the MYMOP is the most appropriate one for use in acupuncture studies (Paterson & Britton, 2003), and the MYMOP was employed in the present study. The key factors that make MYMOP an appropriate outcome measure for researching acupuncture include: it is the most holistic of the alternatives, allowing the patient to define the symptoms they wish to focus on together with a normal activity that they experience as limited by their ill health (Paterson, 1996); it is a brief, easy to administer, problem-specific questionnaire, that is supported with good responsiveness

data; and, it has been developed and validated for acupuncture patients and has been used successfully in a number of evaluations (Paterson 1996).

WSR: Measuring 'process dimensions' of patient experiences. Bell and Kothian (2006) argued that patients of acupuncture experienced 'both global and multidimensional changes', i.e. changes that were both unexpected and unrelated to the presenting condition; they observed that patients were sometimes so focused on these unanticipated changes that they effectively 'forgot' to mention improvements in the symptoms related to the presenting complaint when they were asked about their treatment experience. Bell and Kothian argued that these unanticipated changes were typically not detected by standard outcome measures such as RCTs, a claim that has been supported with evidence from a number qualitative studies (Tippens et al., 2013; Billhult and Sterner-Victorin, 2012; Rugg et al., 2011; Alraek and Malterud, 2009; Hughes, 2009; Paterson and Britten, 2004, 2003, 2007, 2008; Alraek and Baerheim, 2001; Gould and MacPherson, 2001; Cassidy, 1998a/1998b). These researchers have argued that standard outcome measures cannot explore the patient experience of acupuncture and they have suggested that a WSR approach, that employs qualitative methods, will be more effective for the task; Jakes et al., (2014) concurred with this view and argued that a combination of both quantitative and qualitative research methods is needed in order to reveal the full range of outcomes of acupuncture treatment interventions. Other researchers have also argued that by employing qualitative methods in its evaluations, WSR identifies many factors that standard outcome measures have failed to detect, including: how patients have felt and thought about their treatments and the meanings they have ascribed to the intervention generally; how an intervention has integrated with the patient's life and routine; the role patient expectations have played in the healing process; the context by which healing has occurred; and, the outcomes that have been both meaningful and relevant to patients, (Verhoef et al., 2005, 2009). The use of qualitative methods to evaluate acupuncture has an additional benefit, i.e. the data generated by these methods can be used to formulate new hypotheses the testing of which can, by clarifying the conceptual nature of the treatment-outcome link, enhance model validity (Tashakkori & Teddlie, 2003).

Examination of qualitative literature: acupuncture treatment & outcome. Jakes et al., (2014) conducted a systematic review of patients' experiences of acupuncture that involved a specific focus on patients' health beliefs and treatment

experiences. This study investigated 14 qualitative studies originating in five countries, i.e. the UK, Norway, Australia, Sweden and the USA, and which were published between 1998 and 2012; Jakes and colleagues concluded that, as well as being a successful intervention in terms of having had a positive impact on the presenting health condition and symptoms, acupuncture also produced wide-ranging therapeutic outcomes that were not directly related to the presenting health condition. Furthermore, these researchers found that patients experienced additional effects including a greater sense of well-being, reductions in stress, more energy and better sleep.

Jakes et al., (2014) referred to the emergence of a 'therapeutic model of acupuncture consultations' that they described as being characterised by holism, an emphasis on self-care and personal responsibility, and a 'mutual control locus' between patient and practitioner. The studies in the review completed by Jakes et al., (2014) involved a variety of acupuncture treatments, i.e. Traditional Chinese Medicine (n=2), Chinese Medicine (n=3), five-element (n=1), Western (n=1), mixed (n=3), and unstated (n=4), and five of the studies included populations in which some or all of the participants had received acupuncture within the context of a clinical trial. While Jakes and colleagues argued that their study made a contribution to the understanding of acupuncture they also acknowledged that, had their study focused on a single school of acupuncture treatment, it might have produced different conclusions.

WSR: Studies Evaluating Acupuncture as a Complex Intervention

A number of studies have adopted a WSR design involving qualitative research 'nested' within an RCT methodology, (Billhult and Sterner-Victorin, 2012; Paterson et al., 2011; Rugg et al., 2011; Alraek and Malterud, 2009; Alraek and Baerheim, 2001); for example, the study by Patterson and colleagues was an RCT that employed a 26 week MYMOP as the primary outcome measure and examined the outcomes of 5 element acupuncture treatments delivered alongside normal care for 80 patients that were recruited from 4 GP practices, and the study by Rugg and colleagues was a related qualitative study (i.e. nested within the Paterson RCT study) that involved a 'purposive' sample of 20 of the 80 patients in the Paterson study who were interviewed 6 months after treatment. Jakes et al., 2014, argued that RCT studies, such as those cited above, might not be representative of 'natural setting experiences', i.e. a clinic setting, and suggested that the external validity of these studies was poor; a small number of WSR studies have adopted a WSR design without employing RCTs, (Gould and MacPherson,

2001; Cassidy, 1998a, 1998b) and, in view of the criticism made by Jakes and colleagues, they potentially offer insights into acupuncture's efficacy in a clinic setting.

***Investigating 'whole-person' changes in acupuncture trials*.** Cassidy, (1998a/1998b) conducted a cross-sectional mixed qualitative-quantitative study, that investigated patient perceptions of the process and outcome of acupuncture, and their perspectives on acupuncture's treatment effects, and found that the outcomes that people valued included relief of presenting complaints and 'expanded effects of care', i.e. improvements in physiologic coping, including: increases in energy; increases in relaxation and calmness; reduction in reliance on prescription drugs; reduction in the frequency of colds; quicker healing, e.g. from surgery; and improvements in psychosocial coping, such as increases in self-awareness; an increased sense of wholeness, balance and centeredness; improved feelings of well-being; increases in self-efficacy; and all-round positive life changes. Cassidy (1998a/1998b) argued that the study, which analysed both structured questionnaire responses and handwritten stories from 460 users of acupuncture and Chinese Medicine in several centres in the US, indicated that acupuncture patients experienced and valued acupuncture as a form of holistic care.

In a small study (n=11), Gould and MacPherson, (2001) employed quantitative and qualitative methods to investigate patient perspectives on their treatment outcomes; they used patient interviews alongside a questionnaire similar to that used in the Cassidy (1998a/1998b) study. An analysis of the qualitative data showed, to some extent, findings similar to those in the Cassidy, (1998a/1998b) study; the questionnaire data revealed that the patients experienced a range of changes to both their presenting complaint and other factors not directly related to the presenting complaint, including: physical symptoms (75% of respondents); emotional/mental symptoms (67%); 'inner life changes', i.e. improvements in their outlook and attitude towards health (54%); lifestyle behaviour (40%); and, major life changes (27%). Almost half of the small number of patients in the Gould and MacPherson study reported that over time the experience of acupuncture was to change their focus of concern from illness/health to general health and well-being. Analysis of the interview data was largely in line with the findings from the questionnaire, i.e. regarding what was valued by patients the following three themes emerged: changes in symptoms (emotional, mental and well-being); the holistic approach to treatment (e.g. the close practitioner-patient

collaboration); and, the scope for preventing disease, maintaining health generally and improving quality of life and disease prevention, that acupuncture provided.

The findings from the Cassidy (1998a,1998b) and the Gould and MacPherson studies, regarding broader 'whole-person' changes in addition to therapeutic outcomes are in line with whole person changes that have been widely reported in other, purely qualitative, studies; for example, Paterson and Britten (2003) explored the extent to which three subjective health questionnaires measured effects of treatment and they found that, in addition to symptomatic improvement being reported, their patients reported changes in energy levels and relaxation, as well as improvements in coping mechanisms and benefits experienced from the treatment process and the patient-practitioner relationship.

Whole-person changes have been reported in a number of qualitative studies that have examined patient responses to acupuncture treatment provided for a range of specific complaints, including: chronic cystitis (Alraek & Baerheim, 2001); polycystic ovary syndrome (Billhult and Stener-Victorin 2012); chronic health problems (Paterson, 2004, 2007, 2008); medically unexplained physical symptoms (Rugg et al., 2011); hot flushes in postmenopausal women (Alraek and Malterud, 2009); Rheumatoid Arthritis (Hughes, 2009); group acupuncture delivered in a community acupuncture clinic (Tippens et al., 2013). In addition to the above a number of studies have found that multidimensional changes have characterised user's perceptions and subjective experiences of acupuncture treatment, (Jakes et al., 2014; Paterson et al., 2011; Rugg et al., 2011; Paterson, 2007; Paterson and Dieppe, 2005; Paterson and Britten, 2004, 2003; Paterson et al., 2003).

Summary of the Literature and Problem Statement

Several well conducted and large RCT's of acupuncture have, at best, produced inconclusive findings and, at worst, contradictory findings that have generated challenges but have not produced any remedies (Birch et al., 2004). Researchers have argued that traditional methods of scientific investigation, such as RCTs, are inappropriate for evaluating complex health systems like acupuncture because they are reductionist in nature and contrast with the intervention's basic world view that embraces interconnectedness and emergent, non-linear outcomes to treatment that include both local and global changes in the human condition (Bell and Kothian, 2006). RCT's address whether an intervention has an effect statistically, but they do not

recognise, i. the need to measure health as a broader concept than the presence or absence of disease, ii. why the intervention works, iii. how participants are experiencing the intervention, and/or iv. how they give meaning to these experiences.

The Medical Research Council's guidance on complex interventions (Craig et al., 2008) has addressed the issue and has determined that complex interventions such as acupuncture have specific research needs, most notably, the needling and non-needling components as well as the specific theories, concepts and traditional explanations that need to be incorporated within the research paradigm. MRC Guidance suggested that the evaluation of complex interventions requires outcome evaluation, to determine if the intervention works, together with process evaluation, to determine how it works (Moore et al., 2015; Craig et al., 2008). Whole Systems Research (WSR) is an approach that fulfils these requirements and it has been identified as an appropriate method for evaluating acupuncture.

Research using the WSR model is scant and findings converge on the conclusion that global and multidimensional changes characterise acupuncture users' perceptions and subjective experiences of treatment. However, these evaluation studies have several limitations: first, research has typically failed to recognise that there are many different styles of acupuncture and that findings based on researching one particular style, or collection of several styles, cannot be generalised to all other styles. Second, findings have limited generalisability because there has been an under-representation of participants from the range of social and ethnic groups that are representative of the wider UK population, and we have little understanding of whether acupuncture is equally effective for these groups and whether different outcomes are important for different socioeconomic and cultural groups.

The Present Study

Research Rationale and Design

Using a WSR approach, the present study aimed to draw on the experiences of a broad range of acupuncture patients, i.e. men and women of all ages, drawn from a wide range of social and ethnic groups, who were treated at a subsidised clinic that specialised in TCMA and was located in a socially and ethnically diverse area of London. The clinic was situated in one of the most deprived authorities in the country, i.e. according to the Index of Multiple Deprivation (2010) in 2007 it was ranked 18th

most deprived English authority (out of a total of 326 authorities) and the 5th most deprived borough in London (Index of Multiple Deprivation, 2010). The clinic's physical location in an area of social deprivation, and the fact that it provided treatment at reduced fees, i.e. it operated a sliding scale of fees, ensured that the services it offered were accessible to the wide range of people outlined above, most notably its services were accessible to people from the low SES group; furthermore, the patient population presented with the full spectrum of challenging cases of both physical and mental pathology. These characteristics were important in the present study, i.e. possible moderators of the TCMA intervention's effects in a clinic setting were examined.

An objective of study 1 was to explore TCMA efficacy by investigating changes in patient health outcomes over time, as recorded by patients in Measure Yourself Medical Outcome Profile (MYMOP) i.e. recorded changes in the variables, primary symptom, activity and well-being, over six weeks; and to investigate whether a significant difference in Quality of Life (QoL) (individualised health status and wellbeing) would be found between baseline assessment and outcome for acupuncture patients over a 6-week course of TCMA treatment.

An additional objective of study 1 was to explore potential variations in TCMA outcome in relation to both patient's socio-demographic characteristics, i.e. age, gender, ethnicity and social grade, and the wide range of health conditions reflected in the sample.

The objective of study 2 was to explore TCMA patient perceptions and experiences of treatment efficacy in terms of health, wellness and quality of life.

Relevant Acupuncture Research and its Limitations

Research into acupuncture's efficacy that has both, utilised relevant 'holistic' outcome measures and adopted an appropriate methodology, i.e. a mixed methods approach, is sparse; furthermore, as argued by Jakes et al., (2014), few studies have been conducted that have explored the clinic setting experiences of patients and evaluated acupuncture in line with a whole systems research framework, although the studies by Cassidy, (1998a/1998b), and Gould and MacPherson, (2001) are notable exceptions. Jakes and colleagues have also observed that there are various other unresolved problems related to researching and reporting the effectiveness of acupuncture - they argued that the area is full of ambiguities and definitional problems,

e.g. no agreed definition of what constitutes 'Chinese Medicine acupuncture' has emerged from the research.

In their systematic review Jakes et al., (2014) synthesised a range of patient experiences of several different styles of acupuncture, including: TCMA, five-element, and western style acupuncture; they conceded that their findings might have been different had they restricted their study to just one particular style of acupuncture but argued that their methodology was justified because the different schools shared a common conceptual framework. This view conflicts with the views that have been expressed by other researchers, e.g. Birch (1997) argued that researchers have failed to understand that acupuncture is an umbrella term covering a variety of different approaches to treatment, all of which are significantly different, and that the assumption that what is found from testing one will apply to the others is entirely false.
Birch (1997) argued that reviews that examine a variety of different styles of acupuncture will not produce meaningful findings that can be applied to the various individual schools of acupuncture, and Birch and Felt (1999) and MacPherson and Kaptchuck (1997) argued that to generalise findings from studies that have investigated one style of acupuncture, to all forms of acupuncture, is not valid because no one style is representative of all the other styles; they argued that, for results of research in acupuncture to be meaningfully interpreted, researchers must be clear about what styles of acupuncture they have investigated and make clear, in their conclusions, how that selection decision impacts on any conclusions they make.

***Recognising the uniqueness of different acupuncture styles*.** In view of the arguments outlined above (Birch & Felt 1999; Birch, 1997; MacPherson & Kaptchuck 1997), conclusions based on studies that have either investigated different styles of acupuncture without acknowledging that they are different healthcare systems (Hsu et al., 2014; Bishop et al., 2011; Hughes, 2009; Patterson and Britten, 2008), or have failed to clarify exactly what styles of acupuncture were investigated, (Asprey et al., 2012; Billhult and Stener-Victoria, 2012; Griffiths and Taylor, 2005; Gould and MacPherson, 2001; Cassidy, 1998a, 1998b) will have limitations regarding how any conclusions made can be applied to other styles of acupuncture, and the additional limitation that findings will not contribute to the evidence base for the effectiveness of any one specific style of acupuncture. Studies that have focused on a single specified style of acupuncture will not have these limitations, for example, Paterson et al., (2011) investigated a single style of acupuncture, which they clearly specified was 5-element

acupuncture, and consequently produced findings that have contributed to the evidence base for 5-element acupuncture; in a similar fashion the present study selected a single style of acupuncture, i.e. TCMA, and has therefore contributed to the evidence base for the effectiveness of TCMA.

Generalisability in Acupuncture Studies

The research has established that people using CAM reflect a particular demographic profile, i.e. they tend to be female, well-educated and middle class (Davis et al., 2011; Bishop and Lewith 2010; Andrews, 2002; Buono et al., 2001; Cherniack, Senzel, & Pan, 2001; Thomas et al., 2001; Astin et al., 2000), and this demographic is reflected in the patient groups that have been investigated in studies on the effectiveness of acupuncture, i.e. the majority of those studies have involved patient populations that have been predominantly white, female, and middle class; the extent to which findings from these studies can be generalised to the general population in the UK is unknown, i.e. the external validity of these studies in relation to the general population is unknown.

There is a paucity of research that has investigated acupuncture's effectiveness for groups that are representative of people from lower socioeconomic backgrounds and from cultural backgrounds other than white middle class, which has resulted in a corresponding gap in the literature regarding acupuncture's treatment effects within these 'neglected' groups; the meanings of concepts such as well-being, functioning and quality of life have not been investigated in groups that are diverse in terms of ethnicity and SES, as a consequence little is known regarding whether these groups have needs that are different to those of the mostly female, mostly white and mostly middle class groups that have generally been the focus of acupuncture studies.

A small number of studies have investigated the effectiveness of acupuncture in groups that are more diverse in terms of ethnicity and/or socioeconomic status (SES), but they have either failed to do so in a clinic setting or they have failed to do so in the context of a patient population presenting with a wide range of pathologies. For example, Paterson et al., (2011), investigated the effect of adding five-element acupuncture, to 'usual care' for a group of 80 patients with medically unexplained symptoms (MUPS) and approximately half of the patient group, (49%), were from lower SES groups. The primary outcome that they employed in their study was 26-week MYMOP and the findings were that the addition of the acupuncture treatments to usual

care produced improved well-being and health status (MYMOP) that persisted to 12 months. However, the Paterson et al., (2011) study was one part of a larger study involving a qualitative study, reported by Rugg et al., (2011), nested in an RCT, i.e. the Patterson et al., (2011) study; however Jakes et al., (2014) argued that such studies have limitations because they have not investigated acupuncture in a clinic setting - a criticism that also applies to the Alraek and Baerhaim, (2001), Alraek and Malkerud, (2009) and Kliger et al., (2015) studies all of which relied on clinical trials.

There is evidence that usual clinic settings are an important part of acupuncture practice, i.e. in a study that investigated the experiences of acupuncturists involved in RCTs, McManus et al., (2007) found that practitioners felt that their usual clinic setting practice was 'slightly restricted' within trials due to what was an unusual focus on one problem, such as back pain (that focus being one of both the trial and the patient). Barlow et al., (2011) argued that clinical trials, compared to usual clinic settings, provided little opportunity for shared patient-practitioner decision making which undermined 'mutualistic relationships'.

Although Paterson et al., (2011) did to some extent address the issue of diversity their conclusions are limited due to the lack of clinic setting experience of the patients; in contrast, a particular strength of the present study is that it addressed the issue of diversity but did so in the context of a WSR design that did not rely on a clinical trial/RCT, i.e. the present study provided insights into acupuncture's efficacy for treating a diverse population in a clinic setting. Furthermore, the present study investigated the clinic setting experiences of a patient population treated with a specified style of acupuncture (TCMA) and therefore avoided the lack of clarity, regarding what style of acupuncture has been evaluated, that has characterised other studies, such as those completed by Cassidy, (1998a, 1998b), and Gould and MacPherson, (2001), where it is unclear which style of acupuncture was investigated.

In a recent study, that was conducted in the USA Kliger et al. (2015) reported findings from a qualitative study that involved interviewing adults with chronic neck or back pain who had participated in an acupuncture trial. The significant feature of this study is the demographic of the patient population (described by the researchers as 'a lower income, ethnically diverse and medically underserved population'), i.e. the study involved predominantly non-white people of low SES, (59% were on Medicaid, the United States government's subsidised insurance available for low-income people in the

USA, and 53% were Hispanic). The findings from this study are very similar to those from other qualitative studies that have investigated other patient populations.

Kliger and colleagues reported that a particular limitation of their study was the long period of time that elapsed between the patients completing their acupuncture treatments, which were delivered as part of a clinical trial, and the interviews that were conducted for the qualitative study, i.e. on average the time period was 11 months; with such a long gap between the treatment ending and the patients answering questions about that treatment there is the possibility that those answers did not accurately describe the patient experiences of the acupuncture treatment they received, a weakness that was acknowledged by these researchers. Further limitations relate to the fact that, in contrast to the present study which focused on one style of acupuncture and investigated the clinic setting experiences of patients with a wide range of health conditions, the study by Kliger and colleagues investigated more than one acupuncture treatment style, it was not completed in a clinic setting, i.e. it was an RCT study, and only a narrow range of health conditions (primarily neck or back pain) were investigated.

Patterson and Britten (2004) investigated the effectiveness of acupuncture for a broad range of pathologies and approximately a third of their patient sample (n=23) was drawn from NHS clinics, while this might have resulted in a better representation of low SES and ethnic minority groups it was not possible to confirm this as these researchers did not report the demographic profile of their patients.

Pathologies in acupuncture studies. A limitation of the Patterson et al., (2011) study relates to the presenting health conditions of the patients who took part in the study, they all presented with medically unexplained physical symptoms (MUPS). This narrow range of pathology places limitations on the interpretation of their findings, i.e. this study has contributed to the evidence base for the effectiveness of five element acupuncture in the treatment of MUPS, but its conclusions about the effectiveness of five element acupuncture for the treatment of other pathologies is very limited. In a similar fashion, findings from the two Norwegian studies, Alraek and Baerhaim, (2001), and Alraek and Malkerud, (2009), are limited as a result of having investigated acupuncture's effectiveness for treating a single pathology, i.e. menopausal problems in the case of the Alraek and Baerhaim study, and recurrent cystitis in the case of the Alraek and Malkerud study; the same limitation applies to the Kliger et al., (2015) study that focused on chronic neck and back pain. The present study avoided the limitations

associated with the Patterson et al., Study, the two Norwegian studies and the Kliger et al., (2015) study, by virtue of having investigated acupuncture in the treatment of patients presenting with a wide spectrum of mental and physical pathologies.

The two Norwegian studies (Alraek and Malkerud, 2009; Alraek and Baerhaim, 2001), cited above are of particular interest because they both investigated the same style of acupuncture that was investigated in the present study, i.e. TCMA; however, as they involved qualitative research nested within an RCT, they did not investigate the experiences of patients in a clinic setting, in contrast to the present study which did.

The present study is unique, in that it investigated the effectiveness of Traditional Chinese Medicine Acupuncture (TCMA), and examined the possible effects of moderating factors, and combined all the following elements: A WSR methodology; the investigation of patient experiences in a clinic setting; the investigation of a specific style of acupuncture treatment (TCMA); a patient population that had a wide range of mental and physical pathologies; and, a patient population that had a good representation of people from lower socioeconomic backgrounds and a wide range of ethnic groups.

Aims and Objectives

Aim

The aim was to investigate the efficacy of a specific school of acupuncture (TCMA) as a whole complex intervention operating in a clinic setting on a wider representation of users and spectrum of diseases, compared to the typical acupuncture user profile, and to explore potential variations in health outcomes.

Objective

The objective was to use a Whole Systems Research study design involving outcome evaluation, to determine TCMA's effectiveness on Quality of Life (QoL), together with process evaluation, determined by detailed and personal views on patient experiences of treatment.

- Patient data sets of Measure Yourself Medical Outcome Profile (MYMOP), an outcome measure used to investigate changes in health outcomes over time, were extracted and analysed to investigate whether a significant difference in QoL

existed between baseline treatment and outcome for patients over a six-week course of TCMA treatment.

- Patient data sets of MYMOP were extracted and analysed to explore potential variations in TCMA outcomes in relation to both patient's socio-demographic characteristics, i.e. age, gender, ethnicity and social grade, and the wide range of health conditions reflected in the sample.
- Written patient commentaries concerning experiences of TCMA that were provided on patient discharge forms were extracted and analysed via Thematic Analysis.
- Findings were synthesised to establish TCMA's efficacy in a clinic setting for a wide representation of users and spectrum of diseases.

CHAPTER 2

Methodology

The previous chapter reviewed the literature relevant to the present study; this chapter focuses on the research methods and methodology, and epistemological issues. Methodology represents the broad philosophical and theoretical framework of enquiry in which the researcher interacts with the environment (Brewer, 2000) and which gives the research intellectual authority and legitimacy (Denzin, 1978). According to a widely held understanding, enquiry is shaped by a researcher's philosophical and paradigmatic commitments (Willig, 2001; Silverman,1997). Bourdieu (1992) took this further and argued that empirical and technical choices about research cannot be disentangled. This chapter also describes the rationale for the method, the ethical considerations and the processes that were involved in conducting the research.

A mixed-methods, i.e. quantitative (study 1) followed by qualitative (study 2), Whole Systems Research (WSR) methodology was employed to explore measurable improvement in Quality of Life (QoL) over a course of TCMA treatment, and patient perceptions and experiences of their treatment with regards to health, wellness and QoL. The case for using a mixed methods approach is well established in social science research (Silverman, 2000); a number of researchers have suggested that mixed-methods can give greater insights and enhance research credibility and validity (Lavrakus, 1993) and that it often provides the best and most workable solution to a proposed research question, often providing a better understanding than using a single methodology (Creswell & Plano Clark, 2007; Johnson & Onwuegbuzie, 2004). Mixed method designs assimilate different types of data to be analysed at different levels, providing broader results than could be achieved with a single method (Morse, 2009). The technique of data gathering using several sources of data and collection is widely referred to as triangulation (Easterby-Smithe et al., 2002; Denzin, 1978), and it has often been used with qualitative work for its perceived contributions to internal validity (credibility).

WSR incorporates mixed methods and is a methodology that encompasses the specific and the non-specific treatment effects of an intervention such as TCMA; one of the key strengths of WSR is that it enables a whole healthcare system like TCMA to be assessed in the context of the unique explanatory model upon which it is based, which

in turn provides an evaluation of that explanatory model (Verhoef et al., 2006; Verhoef et al., 2005; Cassidy, (1998a/1998b)).

In this study the quantitative data analysis allowed for precise measurement of constructs and comparisons of perceived treatment efficacy in terms of health status and QoL across treatments. The quantitative study was designed to test the hypothesis: *A significant difference in health status/QoL would be found between assessment and outcome for TCMA patients.*

Qualitative text analysis involved the collection of narrative text from patients who had completed questions on the outcome questionnaire at discharge. The mixed method approach allowed for a greater breadth and depth of analysis concerning patient perspectives on the treatment effects and care provided in terms of their health, illness and QoL. The qualitative study focused on the research aims stated in the introduction; to explore patients' experience of TCMA and perceptions of benefits arising from the treatment and care provided at the clinic in terms of health, wellness and QoL.

The methodologies for study 1 and study 2 are presented in this chapter, while the results for study 1 and the findings for study 2 are presented in Chapter 3, which also contains a combined discussion section that integrates the discussion of both study 1 and study 2.

Ethical Approval

Ethical approval for the research, which was a service evaluation using routinely collected outcome data, was granted by City University Department of Psychology on 20 May 2006. (Appendix A, p. 202)

Practice was informed by The British Psychological Society (BPS) Code of Ethics & Conduct (2009). Prior to treatment at a complementary health clinic in London, written consent had been obtained from patients who had been given the option to contribute (anonymised) outcome data for research and evaluation purposes.

Study 1 and Study 2 Methods

Research setting. The clinic had been providing acupuncture treatments for over a decade; all the acupuncturists at the clinic were registered with the British Acupuncture Council and they practiced acupuncture as part of the Traditional Chinese Medicine system. The clinic offered treatments at reduced fees, i.e. it operated a sliding scale of fees, which together with its physical location in area of relevant deprivation,

ensured that the services it offered were accessible to a wide range of people, including people from lower socio-economic groups. This feature of the clinic, regarding accessibility, was reflected in the composition of the patient population, i.e. men and women of all ages from a wide range of social and ethnic groups. Furthermore, the patient population covered the full spectrum of challenging cases of both physical and mental pathology with patients referred with, or without, the recommendation or suggestion of their GP.

The routinely collected information provided by the clinic did not include details regarding whether or not patients had any previous exposure to acupuncture and the level of any previous exposure in the patient sample for this research is unknown. In a personal communication, the clinic manager explained that on an application for treatment, patients were placed on a waiting list and offered the first available start date.

All the patients in the sample selected for this research completed six consecutive TCMA treatments delivered over a 6-week period, i.e. this was the inclusion criterion, the first of these sessions was one hour long with subsequent sessions lasting 45 minutes. Patients seeking a second course of treatment were placed on a waiting list.

Study 1: The Quantitative Component.

Aim

This part of the research addressed the question, 'does TCMA produce measurable improvement in Quality of Life (QoL) over a six-week course of treatment?

The study was designed to test the hypothesis: *A significant difference in health status/QoL would be found between assessment and outcome for TCMA patients.*

Sample

Data used in study 1 was obtained from 208 patient files held at the clinic for patients treated with TCMA, between February 2007 and March 2008, and who fulfilled the inclusion criteria of having attended 6 consecutive treatment sessions from baseline treatment, irrespective of outcome or symptom.

Presenting health conditions were cited by patients on their MYMOP forms, and included: neck, shoulder and back complaints; headaches and joint problems; and emotional and functional problems such as depression, anxiety, lack of focus and hyperactivity. These conditions were classified according to The International

Classification of Primary Care (ICPC-2) (2003), a classification method for primary care which allows for the classification of the patient's reason for encounter (RFE) developed by the WONCA International Classification Committee (WICC).

Characteristics of the sample according to symptom, are presented in table 2.1; to ensure adequate cell sizes for statistical analyses, these symptoms were aggregated into the three categories presented in table 2.2 (Musculoskeletal, Psychosocial, and Other), from which it can be seen that the most frequent clinical problem treated was Musculoskeletal (40.4%), followed by Psychosocial (33.2%), and Other (26.4%).

The demographic characteristics of the 208 patients are also shown in Table 2.2, from which it can be seen that the majority of patients were aged 40-59yrs (41.8 %, n=87), followed by those under 40yrs (29.8%, n=62) and the 60+ age group (28.4 %, n=59); the patient sample was predominantly female, with 134 females (64.4 %) and 74 males (35.6 %); the sample was diverse in terms of the ethnicity with the majority identified as White British (59.1 %, n=123), followed by Black (16.8%, n=35), Asian (13.9 %, n=29), Mixed/Other (8.2 %, n=17) and Unknown (1.9%, n=4).

Unusually, for populations of patients that have received acupuncture treatment, over half of the sample (52.9%, n=110) was drawn from lower socio-economic groups, i.e. from social grades C2 D E (skilled manual workers, semi-skilled and unskilled manual workers, lowest grade workers, and unemployed and on state benefit) while just under half (47.1%, n=98) came from social grades A B C1 (higher and intermediate managerial workers, administrative, professional, supervisory and managerial (junior), clerical, administrative and professional occupations). A fact which, as stated above, probably reflected the improved accessibility of the clinic's services achieved through the reduced fees and the clinic's location.

Table 2.1: Characteristics of the sample (*n*=208) according to symptom

SYMPTOM	%	(*n*)
Anxiety/Panic	3.4	7
Arm	1.0	2
Back	19.7	41
Circulatory	.5	1
Depression	10.6	22
Digestive	6.3	13
Ear	.5	1
Endocrine/Metabolic	1.0	2
Eye	.5	1
Fatigue	4.3	9
Feet	1.0	2
Female Genital & Breast	9.6	20
General unspecified	.5	1
Hand	1	2
Hip	1.4	3
Insomnia	4.8	10
Knee	3.4	7
Leg	2.4	5
Male	.5	1
Memory/Concentration	1.4	3
Neck	5.8	12
Neurological	4.8	10
Respiratory	2.4	5
Shoulder	4.8	10
Stess	8.2	17
Substance Abuse	.5	1

Table 2.2: Characteristics of the sample (n=208) according to gender, age, ethnicity, social grade and health condition

Category	Sub-Category	% (n)
Gender	Male	35.6 (74)
	Female	64.4 (134)
Age	Under 40	29.8 (62)
	40-59	41.8 (87)
	60+	28.4 (59)
Ethnicity	White	59.1 (123)
	Black	16.8 (35)
	Asian	13.9 (29)
	Mixed/Other	8.2 (17)
	Unknown	1.9 (4)
Social grade[a]	[b]A B C1	47.1 (98)
	[c]C2 D E	52.9 (110)
Symptoms	Musculoskeletal	40.4 (84)
	Psychosocial	33.2 (69)
	Other	26.4 (55)

Note

[a]Socioeconomic Status (SES) classified according to the the NRS social grades system of demographic classification.

[b] higher and intermediate managerial/administrative/ professional, supervisory, clerical, junior managerial/administrative/professional

[c] Skilled manual workers; Semi and unskilled manual workers; lowest grade workers, unemployed, on state benefit.

Of the 208 patient files, 54% (n = 112) cited restricted activity associated with symptoms on their MYMOP forms; Figure 2.1 presents a profile of these patients from which it can be seen that the most common restricted activities were lifting and bending (18%), physical activity (14%), sitting/standing (12%), walking/shopping (11%) and working (11%).

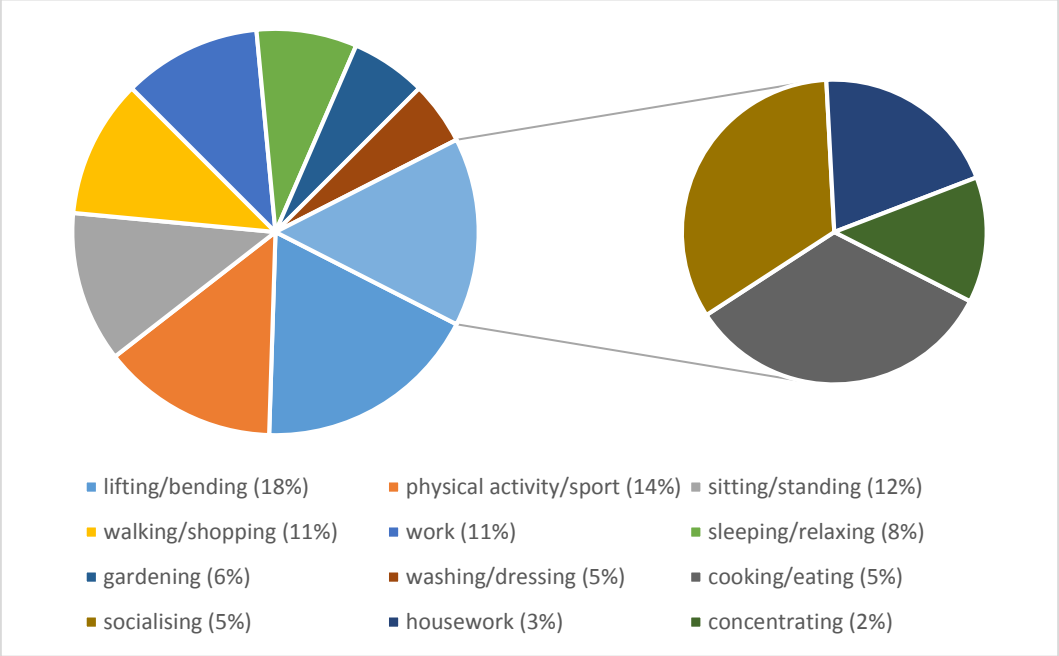


Figure 2.1: Restricted Activity Associated with Symptoms (n = 112)

Outcome measures. Evidence based practice is at the centre of all National Health Service initiatives and it is consequently necessary to use outcome measures in order to evaluate medical interventions or treatments. Medical interventions are intended to improve the quality of life by maintaining or improving functioning and wellbeing and it was therefore important to measure patients' subjective experiences of both their illnesses and the care they received in treatment.

Historically, patient-specific or patient-generated outcome measures (which allow patients to both choose and describe their own dimensions of concern as well as make personal assessments) were rarely, if ever, incorporated in the healthcare evaluation process; healthcare evaluations were mostly condition specific and were completed without patient consultation, i.e. patient views regarding the uniqueness of their health issues were not a part of healthcare evaluation. This situation changed when the concept of wellbeing was incorporated into treatment generally and patients became more empowered to contribute to their treatment outcomes. Historically, improvements in a patient's condition, as shown by some objective criterion (as assessed by the clinician), was sufficient to conclude that treatment had been successful, but this practice waned as improvements in patient care developed, and success defined by the healthcare professional alone, ceased to be any guarantee that the patient would be satisfied that 'all was well', particularly when they believed that their personal concerns

had not been addressed. It is now widely accepted people's subjective perceptions of health and illness vary considerably and often do not correspond to the conclusions that health professionals are likely to reach based on their objective standards of assessment.

With the emergence of wellbeing as an important concept that needed to be included in the healthcare professional's narrative the popularity and general acceptance of the process of evaluating health and treatment interventions purely in terms of an 'objective disease-based' model diminished considerably. One of the anomalies in medical practice is that a patient's perception of wellbeing may be discordant with their 'objective' health status. For example, a person might complain of feeling ill in spite of medical science asserting that they are not ill, but the failure to detect a cause of a supposed illness will not be a remedy for the patient. Equally, a person might be ill without complaining of any illness, i.e. there has long been evidence that many people have lived with pathologies of which they have been unaware (Bowling, 1991). These anomalies, as well as the increased involvement in outcomes that patients demanded, led to developments in quality of life research and increased attempts to produce measurement instruments that retained the important psychometric properties they needed to have and incorporated individually generated content and quality of life measures.

The importance of subjective perceptions of health and the focus on the measurement of function and quality of life were acknowledged in a review of outcome measures for primary care (Wilkin & Hallam, 1992). According to Ruta et al. (1998), outcomes are not single 'before or after' events but rather they are usually related to patients' progress over time. Ruta and her colleagues argued that an outcome measure should have a number of specific features: it should measure both the aspects and the effects of patient-generated concerns; it should allow the patient to self-score their generated variables; it should be a sensitive measure of within person change over time; and, it should be able to be applied to all illness seen in primary care as well as being capable of measuring aspects of a wide variety of care. These researchers also argued that outcome measures should be brief and simple to follow, which is a very practical consideration, i.e. patients completing outcome measures will often be feeling ill, particularly at the first consultation, in view of which it is very important that Quality of Life (QoL) measures involve items that are short and simple to understand, and that the tool itself can be easily and quickly administered; the work of Patterson (1996) and her

Measure Your Own Medical Profile (MYMOP) has made an important contribution in this field.

The Measure Yourself Medical Outcome Profile (MYMOP). The Measure Yourself Medical Outcome Profile (MYMOP) is a simple to complete questionnaire that was designed by Paterson (1996) and developed to evaluate clinical outcomes as assessed by patients (Paterson, 1996). MYMOP was intended to be applicable to a broad spectrum of illnesses seen in primary care, and it was developed primarily for use with physical illnesses. The approach of asking patients to rate how much their clinical condition has improved or worsened over a specified period of time has a long history in clinical research (Jenkinson 1994, Fitzpatrick et al., 1992) and utilisation of the MYMOP as a tool for evaluation has long been popular in both the allopathic and the complementary and alternative (CAM) literature (Paterson, 1996).

The selection and origins of the items on the MYMOP. The MYMOP was adapted from the patient generated index (PGI), which was developed by Ruta, Garratt, and Leng (1994), and it was among the first of the patient-generated measures to be developed. The PGI is a health-related quality of life (HRQoL) measure that was derived from Calman's definition of quality of life, i.e. 'A good quality of life can be said to be present when the hopes of an individual are matched and fulfilled by experience.' (Calman, 1984, pp. 124-125).

The PGI requires respondents to nominate the areas of their lives which are most affected by their health condition, following which they rate the severity of the effects of those nominated conditions and then weight their relative importance. In completing the PGI patients 'generate' their own symptoms and measure their personal functioning and wellbeing; for example, the measure directs individuals with back pain to list the five most important aspects of their lives that are affected by their condition, and then to score the severity of each aspect listed; this contrasts the outcome measurement scales that suggest symptoms, derived from the opinions of 'professional experts', which were contained on outcome measurement scales prior to the PGI. This concept of a patient-generated QoL measure was further developed in Paterson's MYMOP (Paterson, 1996). A patient generated health status questionnaire, the MYMOP is both symptom specific and sensitive to the person's whole situation, i.e. as mentioned above it includes the monitoring of a daily activity as well as the person's general wellbeing. MYMOP entails a one-page schedule completed with the therapist at baseline in order to establish

the main concerns of the patient at the time of referral and to measure the severity of those 'concerns' as perceived by the patient.

The MYMOP has four items, i.e. Symptom 1, Symptom 2, Activity, and Well-Being, and each item is scored on a seven-point scale, with 0 labelled 'as good as it could be' and representing the best possible score for the variable, and 6 labelled 'as bad as it could be' and representing the worst possible score. For example, if for the variable Symptom, the patient selected 'back pain', then a score of 0 would represent no back pain, and a score of 6 would represent very severe back pain. The baseline MYMOP is completed with the help and guidance of the practitioner, but the administration instructions emphasise it is the patient's own words that must be used, e.g. when selecting Symptom and Activity (the actual item wording for each of these variables is presented in Table 2.3). Symptom 1 and Well-Being are obligatory scales and must be completed for the MYMOP form to be valid; Symptom 2 and Activity are optional items. An additional variable, i.e. the MYMOP profile score is generated by calculating the mean of all scales that have been marked, e.g. if only Symptom 1 and Well Being were scored then the Profile score was the sum of these two scores divided by 2, but if Symptom 1, Activity and Well Being were scored, then the Profile score was the sum of these three scores divided by 3. In the present study, four variables were measured: Symptom, Activity, Well-Being and QoL, the latter being the MYMOP profile score outlined above. (an example MYMOP form is presented in Appendix B, p. 205).

The MYMOP's validity and responsiveness. The present study investigated change in QoL and TCMA treatment over time, i.e. the study examined a measure of change within individuals over time. Clearly, the properties of any measurement tool employed in such a study must have the appropriate psychometric properties, i.e. as explained by Kline (2000) as a minimum requirement, clinical outcome measures should be able to demonstrate internal reliability and evidence aspects of construct validity. Although Kline refers to validity and reliability in the context of the measurement instrument employed in this study the two important properties are validity and responsiveness; the property of responsiveness includes the concept of reproducibility and the denominator of the responsiveness index is the variability in score in stable subjects and therefore, for evaluative instruments, responsiveness replaces the concept of reliability. (Foster & Cone,1995).

Foster & Cone (1995) defined validity as the extent to which scores on a measure relate to scores on other measures; they argued that this definition was more general than the usual one, that scores on a measure are valid if they measure what they purport to measure. While this type of validity was important in the context of this study, it was only one of several types of validity that needed to be considered.

A measurement tool can be assessed in terms of its face validity, i.e. the extent to which it appears, to the participant, to be an appropriate tool for the purpose that it is being used. Although face validity refers to the respondent's perception of the tools appropriateness, as opposed to the actual properties of the instrument, it is nevertheless an important quality of any measurement tool because it ensures the co-operation, motivation and compliance of the participant/respondent.

Content validity is another important type of validity and refers to the extent to which a measure reflects the particular intended domain of content and excludes unintended (i.e. irrelevant) domains of content while maintaining a balance of indicators of the construct being measured (Haynes, Richard, & Kubany, 1995). Content validity is important because it determines the extent to which the measurement tool is comprehensive in terms of measuring what it is intended to measure, and exclusive in terms of measurements not being contaminated by irrelevant factors. The key issues in relation to content validity are item selection and category definitions; first, the target categories to be measured must be clearly defined, and second, the items must be constructed and selected on the basis of those well-defined categories.

A set of scores have construct validity if they correlate with scores, obtained from other already validated measures, in hypothesised ways; it can be demonstrated by comparing the results of several different tests for validity; for example, concurrent, convergent and discriminative validity studies. Scores have convergent validity if they correlate with scores obtained from other established methods of assessing the same construct, and scores have discriminant validity if they do not correlate with scores obtained from measures that are known not to measure the construct being measured, i.e. scores which theory predicts should be independent.

Criterion-related validity is another important type of validity and it has two forms, i.e. predictive and concurrent validity. Concurrent validity is high when scores on a measure of the respondent's current performance correlate with scores obtained from an alternative, equivalent and validated measure of that performance (Kline, 2000). Predictive validity is demonstrated when a measure is shown to be effective in

predicting indicators of a construct, i.e. a measure with high predictive validity is one that can predict a future event such as the development of a specific disease at some point in the future (Haynes, Richard, & Kubany, 1995).

The validity and responsiveness of the MYMOP have been calculated in a number of studies conducted both here in the UK and in the USA (Paterson, 2003) and tests of validity and responsiveness indicate that the MYMOP correlates with health status and perceived improvements in health. Validation strategies for the MYMOP include a demonstration of its content validity via comparison of MYMOP with other widely used QoL measures, criterion-based approaches and correlation studies. The validity of the MYMOP is evident from its ability to detect different degrees of change in relation to change scores and in acute and chronic conditions; its criterion validity has been shown by its correlations with SF-36 scores (Paterson1996).

The MYMOP appears to demonstrate greater sensitivity over competing QoL measures, i.e. questions have been deemed to be more sensitive to change than the domains of the short form health profile, SF-36, a generic measure of outcomes (Ruta et al., 1998). It is therefore likely to be more appropriate for assessing patients complaining of minor or chronic health problems and it has been identified as the best outcome measure for identifying subtle changes over time.

The MYMOP's validity and responsiveness have been corroborated by Paterson and Langan et al., (2000), i.e. they found that the MYMOP's responsiveness index relating to minimal clinically important change was greater than two QoL measures (the MOS-6A and the EQ-5D). Furthermore, research carried out by Hull et al., (2006) established that the MYMOP was the most useful of four measures (including SF-36, global clinical change and patient satisfaction) used to evaluate clinical outcomes associated with a course of acupuncture treatments.

Paterson et al., (2000) found that the change in MYMOP scores at two weeks showed a consistent gradient across the spectrum of clinical change; the gradient, and the difference between scores for 'a little better' to 'about the same', were significant across all MYMOP scales except Wellbeing. Practitioners reported that the Wellbeing scale was clinically useful, especially in the context of chronic disease, where an improvement in wellbeing may be a more realistic aim than a large improvement in symptoms or function.

Table 2.3: Item Wording for MYMOP variables

Variable	Wording
Symptom	Choose one or two symptoms (physical or mental) which bother you most. Write them on the lines. Now consider how bad each symptom is, over the last week, and score it by circling your chosen number.
Activity	Now choose one activity (physical, social, or mental) that is important to you, and that your problem makes difficult or prevents you from doing. Score how bad it has been in the last week.
Well-Being	Lastly, how would you rate your general feeling of wellbeing over the last week?

The MYMOP questionnaire validity has also been considered in terms of the relationship between 'change in scores' and 'clinical outcome' (as assessed by the patient's physician) and the construct validity of MYMOP was evidenced by the gradient and magnitude of change scores of patient-perceived change in clinical condition and by the relationship between score change and the physician's assessment of clinical outcome

The MYMOP is a validated patient generated outcome measure (Paterson, 1996) and there is evidence for both its validity and responsiveness; it has been used successfully for evaluating patient outcomes for both allopathic and complementary therapy treatment for a range of problems and it has demonstrated the ability to discriminate between different population and patient groups. It has been used across groups differing in socio-demographic characteristics, diagnosis and disease severity, and it allows for comparison with normative data (Paterson & Langan et al, 2000; Hull et al, 2006, Paterson, 1996, Paterson & Britten, 2000; Paterson & Britten, 2003, Peters, Pinto & Harris 2000; Thomas, Strong & Luff, 2001). The MYMOP is arguably the most valid and responsive generic health status assessment, for use alongside disease specific measures, or when disease specific measures are inappropriate or difficult to employ. The MYMOP was used in the complementary health clinic, that was the focus of the present study, to assess patient outcomes from 2001 onwards.

Materials and Methods

The outcome measure used in this study was the Measure Your Medical Outcome Profile completed at baseline (treatment 1), follow up (treatment 2), follow up (treatment 3) follow up (treatment 4) follow up (treatment 5) and follow up (treatment 6).

MYMOP: data collection and scoring. Patients were asked to list the five most important areas of life that were affecting them, and they were then instructed to select one or two related symptoms that they had considered to be important (i.e. symptoms that they had wanted to improve) as well as an activity that was affected by those symptoms(s). The selected symptom(s) and activity were entered on the MYMOP form and these variables, together with wellbeing, were rated on a 7-point scale as described above (p. 72). MYMOP forms had been completed at each consultation which ensured that any clinical changes in the measured variables (i.e. symptoms, activity and wellbeing) were monitored (NB a reduction in scores indicated an improvement in the patient's rating of their own health, whereas an increase in scores indicated an adverse change). NB in a personal communication the centre manager disclosed that the MYMOP administration instructions related to nominating a second symptom had not always been followed by the clinic's practitioners, i.e. the instructions state that symptom 2 is optional but when nominated it must be part of same problem, for this reason in the present study symptom 2 was disregarded.

Data collection. MYMOP clinical outcome scores for the sample were collated and these data items were entered by an administrator into Microsoft Excel spreadsheets; further information about gender, age, ethnic groups and social grade, was also obtained from the patient intake forms attached to the files and this data was analysed retrospectively and provided the basis for this study

Data screening & missing values. The data was screened for input accuracy and missing data; missing scores were identified in the Activity MYMOP profile scores, i.e. out of the 208 patients, 46% (n=96) was identified as having missing Activity MYMOP profile scores. Hair et al., (1998) reported that there is no single method best suited in every situation for dealing with missing scores and argued that a reasoned judgment can be made. The pattern of missing scores in this study suggested that data was missing completely at random and, given that the Activity scores were optional for the MYMOP Profile score, that the MYMOP Profile score is the mean of all the individual item scores (Paterson 1996), and that the data set was very large, the decision was made to

continue the analysis on the basis that, n = 112, for the MYMOP Activity profile scores. It is common practice to use mean substitution whereby each missing value for a variable is replaced with the average of the observed values (Schafer and Graham, 2002), and this study used the mean substitution method for dealing with missing data of the Activity MYMOP profile scores.

Data Analysis

Statistical analyses were performed using the SPSS statistical package program SPSS 17.0 (SPSS, Chicago, Illinois). Within subjects repeated measures ANOVA were carried out to compare MYMOP profile scores across treatments (as well as the symptom, activity and well-being scores). P values for the within-subject effects in repeated measures analyses were based on Huyndt-Feldt corrections for sphericity.

Sub group data analysis. Subgroup analyses were treated as exploratory data analysis for the purpose of generating further hypotheses (Altman, 1991). Subgroup analysis followed the same procedure as that set out for the primary analysis but examined the effects of treatment on different demographic categories, or for different symptoms. One-way analyses of variance (ANOVA) and independent t-tests were carried out on the data as appropriate, in order to assess the change from baseline to follow-up.

Statistical tests. The data analysis recommended for MYMOP suggests the use of parametric methods for large sample sizes, and scores are quoted as means and standard deviations (Patterson, 1996). Parametric methods have been used to assess reliability and validity and have been applied in the development of normative data, to assess change over time, (Paterson, 1996). For the purpose of this study a parametric approach was applied as recommended for MYMOP.

Examining suitability of the data for parametric statistical analysis: the assumptions of parametric tests. In order to run a parametric test, four assumptions need to be met: (1) data needs to be normally distributed, (2) data needs to demonstrate homogeneity of variance, (3) data must have interval properties, and (4) data needs to show independence.

Normal distribution. An examination of the participants' MYMOP scores revealed that none of the score distributions varied significantly from a normal distribution. Skewness (the distributions' symmetry) and Kurtosis (the peakedness of the distribution) are two components of normality; the shape of the distribution can be

seen visually and the values of skewness and kurtosis in a normal distribution should be zero. Histograms were used to examine the data for normal distribution at Baseline, followUp1, followUp2, followUp3, followUp4, followUp5 and Reduction in scores values **(**Appendix C, p. 206).

Homogeneity of variance. To test for homogeneity of variance Levene's test was applied; if Levene's test is significant ($p < .05$) the variances are significantly different and the assumption of homogeneity of variances has been violated; if Levene's test is non-significant ($p > .05$) then the assumption is tenable as the variances are equal.

Interval data & independence. The assumptions of interval data and independence cannot be tested via statistics. However, MYMOP profile scores are measured on a 7-point scale and satisfy interval data requirements. This study employed a repeated measures design thus scores were non-dependent for a given patient; however, behaviour between different participants should be independent i.e. patient responses should be independent.

Effect size and statistical power. Statistical power, (the probability that an effect will be found if there is one) is dependent on the size of the sample, the number of groups compared and the expected size of the effect. The larger the effect size posited (other factors such as significance size and sample size being equal) the greater the power of the test (Cohen 1988). This study employed the traditional .05 criterion of statistical significance (although a common convention is to get at least 80% power, 95% power should be ideally employed). Effect size was measured by Cohen's d statistic; by convention, values of 0.2, 0.5, and 0.8 are defined as small, medium, and large effects, respectively (Field, 2009).

As this study aimed to assess the effects of a clinical intervention, mean differences (effect sizes) which were significant were required. The comparison of MYMOP profile scores across treatments using within-subjects repeated measures ANOVA's and independent t-tests would produce a measure of 'effect size' on the basis of the difference between the mean scores. This effect size conveys important information about the magnitude of the treatment difference, the larger the value the greater the degree to which the phenomena under study is present (Cohen 1988).

Confidence intervals. There is some concern in the literature relating to the use of `p' values in research (Pocock 1983, Pocock et al., 1987, Altman 1992, Sackett 1997); in particular, criticism has focused on the failure of research to include confidence intervals, which may be important in conveying whether clinically important

differences exist (Pocock et al., 1987). The two values that define a confidence interval indicate the range of values of the true effect that is consistent with the data (Altman 1992); for example, if a sample size is chosen randomly, then a 95% confidence interval means its value will lie between the range 95 times out of 100. In research the confidence intervals of primary interest are those for the treatment difference as they provide a valid graphical comparison of treatment means (Pocock 1983).

Results of the statistical analysis for study 1 are reported in the following chapter (Chapter 3), where, in order to get a true picture of the range of effect size and to provide information which is clinically relevant, results of the t-tests are reported, together with the mean difference (size of the effect) and confidence intervals for the mean difference.

Study 2: The Qualitative Component.

Aim

The aim of Study 2 was to gather additional information to complement and support the results of Study 1, and to collect other important or specific ideas.

This additional data gathering process provided the potential for elaborating on the results, which offered potentially useful and important information to guide future research. This was achieved by exploring patient's experience of TCMA, via qualitative orientated questions that were included on patient discharge outcome questionnaires.

A qualitative methodology was applied to examine the aim, i.e. 'to explore patients' experience of TCMA and perceptions of benefits that arose from the treatment and care provided at the clinic in terms of health, wellness and QoL'.

Methodology

Design. A qualitative non-experimental design was used in this study, which allowed the exploration of the experience of the participants as seen through their eyes as opposed to testing preconceived hypothesis or predictions. The research sought to determine the patients' experience of TCMA and their perceptions of the treatment effects and care provided in terms of their health, wellness and QoL. This treatment satisfaction question was posed as an open-ended question on an outcome questionnaire at the end of treatment. Thematic analysis was used to inductively identify themes that emerged from the data.

Sample. The patient sample for study 2 (n = 117) was generated from the patient sample used in study 1 by applying the inclusion criteria that only those patients who had answered questions on their outcome questionnaire at discharge (Appendix D) would be included in study 2, this resulted in just over half (56.3%) of the patient sample used in study 1 being included in study 2.

Characteristics of the sample according to symptom, are presented in table 2.4, and, as for study 1, these symptoms were aggregated into the three categories presented in Table 2.5 (Musculoskeletal, Psychosocial, and Other), from which it can be seen that the most frequent clinical problem treated was Musculoskeletal (47.9%), followed by Psychosocial (36.8%), and Other (15.4%).

The demographic characteristics of the 117 patients are also shown in Table 2.5, from which it can be seen that the majority of patients were aged 40-59yrs (56.4%, n=66), followed by those under 40yrs (24.8%, n=29) and the 60+ age group (18.8%, n=22); the patient sample was predominantly female, with 85 females (72.6%) and 32 males (27.4%); the sample was diverse in terms of the ethnicity with the majority identified as White British (47.9%, n=56), followed by Black (24.8%, n=29), Asian (17.1%, n=20), Mixed/Other (6.8%, n=8) and Unknown (3.4%, n=4). Nearly two thirds of the sample (60.7%, n=71), was drawn from lower socio-economic groups, i.e. from social grades C2 D E (skilled manual workers, semi-skilled and unskilled manual workers, lowest grade workers, and unemployed and on state benefit) with just over a third (39.3, n=46) drawn from social grades A B C1 (higher and intermediate managerial workers, administrative, professional, supervisory and managerial (junior), clerical, administrative and professional occupations).

Of the 117 patients, 59% (n = 69) cited restricted activity associated with symptoms on their MYMOP forms; Figure 2.2 presents a profile of these patients from which it can be seen that the most common restricted activities were lifting and bending (26%), sitting/standing (16%), physical activity (13%), walking/shopping (12%) and working (11%).

Materials and procedure for the study. The clinic had, prior to treatment, obtained written consent from patients to contribute (anonymised) outcome data for research and evaluation purposes. On completion of their course of TCMA, patients were asked to provide written statements concerning treatment satisfaction relating to their experience of treatment and care provided at the clinic, particularly in relation to health, wellness and QoL.

The outcome questionnaire at discharge (Appendix D) required patients to answer two questions (and invited them to make additional comments):

What is your opinion on the treatment and care provided at the clinic?

Can you comment on your satisfaction with treatment effects on your illness, health and general wellbeing?

Table 2.4: Characteristics of the sample (*n* = 117) according to symptom

SYMPTOM	%	(*n*)
Anxiety/Panic	4.3	5
Arm	1.7	2
Back	28.2	33
Depression	14.5	17
Digestive	5.1	6
Ear	.9	1
Female Genital & Breast	6.8	8
Hand	.9	1
Hip	1.7	2
Insomnia	5.1	6
Knee	3.4	4
Leg	3.4	4
Memory/Concentration	2.7	3
Neck	6	7
Neurological	1.7	2
Respiratory	.9	1
Shoulder	2.7	3
Stess	10.3	12

Qualitative research issues. Many researchers believe that the criteria traditionally used to evaluate the scientific value of quantitative research in psychology (which were discussed in study 1) are not, in their current form, meaningful in terms of applicability to qualitative research (Willig, 2001; Denzin & Lincoln, 2005). Whilst acknowledging the philosophical and practical differences of researcher's criteria, issues of reliability, validity, generalisability is what establishes credibility; according to Silverman (2001) the concern with reliability shown by quantitative methods needs to be expressed in qualitative research. This research study used guiding criteria for establishing its quality, not necessarily as a prescriptive checklist criteria method of demonstrating validity, which was criticised by both Babour (2001) and Blaxter (2000), but as a way of providing indicative guidance to the reader, of the procedures that were applied to the research.

Table 2.5: Characteristics of the sample according to gender, age, ethnicity, social grade and health condition (n=117)

Category	Sub-category	% (n)
Gender	Male	27.4 (32)
	Female	72.6 (85)
Age	Under 40	24.8 (29)
	40-59	56.4 (66)
	60+	18.8 (22)
Ethnicity	White	47.9 (56)
	Black	24.8 (29)
	Asian	17.1 (20)
	Mixed/Other	6.8 (8)
	Unknown	3.4 (4)
Social grade[a]	[b]A B C1	39.3 (46)
	[c]C2 D E	60.7 (71)
Symptoms	Musculoskeletal	47.9 (56)
	Psychosocial	36.8 (43)
	Other	15.4 (18)

Note.

[a]*Socioeconomic status (SES) classified according to the* The NRS social grades system of demographic classification.

[b]higher and intermediate managerial/administrative/professional, supervisory,clerical,junior managerial/administrative/professional

[c] Skilled manual workers; Semi and unskilled manual workers; lowest grade workers, unemployed, on state benefit.

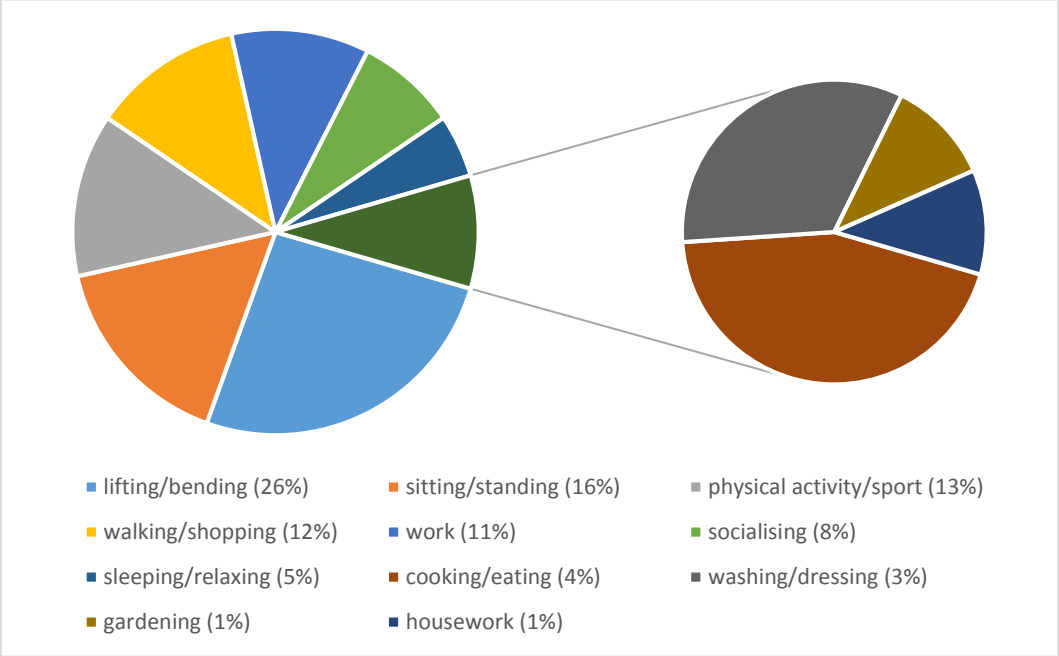


Figure 2.2: Restricted Activity Associated with Symptoms (n = 69)

The present research utilised qualitative methods that best answered the proposed research questions as well as keeping with the overall pragmatic philosophy of the research; published guidelines were rigorously followed and documented appropriately, ensuring reliability of results.

Inter-rater reliability ensured that the analysis derived themes in a standardised way (Silverman, 2001). Textual responses were read and re-read many times to ensure that patients' viewpoints, experiences, thoughts and feelings were interpreted and portrayed accurately in the research. Moreover, time spent discussing and explaining research findings with researchers in the field was extremely useful, this, in addition to reading around the field of enquiry, ensured theoretical validity. The mixed methods research methods utilised in this research further facilitated the validation of research findings; whereas each method can produce knowledge that is limited, a combination allows for elaboration, supplementation, correction or modification of the limited insights gained for each single method (Yardley, 2000).

Reliability is concerned with the degree of consistency and the manner in which the research is conducted (Kvale, 1996); Silveman (2016) argued that applying appropriate and rigorous qualitative methods should itself produce reliable results. The generalisability of the findings of this research is respectable with particular reference to ethnicity, socioeconomic status and a wide variety of health problems

reflected in the UK population. The findings provided an adequate degree of representativeness; furthermore, a comparative method was used for promoting generalisability, i.e. Perakyla, (1997) suggested obtaining information about relevant aspects of the population of interest, e.g. from the available literature, and then comparing the information with the results of the study, supporting or similar findings would then help in establishing generalisation of results.

The present research has addressed Yardley's (2000) broader quality criteria principles that are applicable to all research; i.e. sensitivity to context, coherence and transparency, commitment and rigour, and, impact and importance. Sensitivity to context was demonstrated, in the first instance, by the researcher's rationale for choice of methodology (Smith et al, 2009) and was further demonstrated throughout the text analysis process by the sensitivity to the theoretical context of the topic studied, i.e. previous relevant empirical literature was taken into account during the process; plausibility or credibility of codes and themes in the light of existing knowledge was continuously contemplated; and, in the text analysis, the researcher remained sensitive to the context of their own interpretations and ensured that equal attention was paid to similar or contradictory accounts.

Sensitivity to context was also demonstrated to the reader by the multiple verbatim extracts that accompanied the researcher's interpretations; the extracts illustrated what had been said and helped to provide a representative portrayal of responses from the target population which ensured representativeness and generalisation. Coherence was achieved through the careful reading of themes for their coherent presentation and interpretation to the reader with adequate explanation.
In addition, the research report provided sufficient detail of the methods and analysis employed to ensure transparency to the reader so that they could evaluate the research's merits and limitations and enable a judgment regarding whether or not the text supported the conclusions drawn. Commitment to rigour was shown throughout the research through the use of appropriate and rigorous qualitative methods; through continual checking and questioning of the decisions or procedures used in the research to ensure they were appropriate and accurate, i.e. in order to produce reliable and replicable results; through the researcher's immersion and engagement with the topic and the research methodology, i.e. in order to tease out the most relevant and important aspects prominent in the text and going beyond superficial descriptions to achieve the depth and breadth of analysis demonstrated in this research.

The present research demonstrated the required craftsmanship through explicit documentation of researcher inputs within appropriate stages of the research, as Willig (2001) suggested, this explication of the steps and decisions made throughout the research process helps to promote accurate interpretations, which in turn helps to promote validity. Furthermore, the impact and importance of the research, in terms of theory and practice for both patients and health professionals, have been clearly communicated to the reader.

Finally, the researcher is aware of the need for the reliability validity evaluation criteria to reflect, and be compatible with, the epistemological framework of the research that is being evaluated (Willig, 2001); these issues have been considered in the section presented below.

Text Analysis

Thematic Analysis was chosen by the researcher because it served to identify common themes, that were present in the text, across the experiences of a wide variety of participants. The aim was to break down the text into meaningful and manageable segments of information which, on interpretation, would answer the research question posed.

As a method Thematic Analysis is flexible and responsive to text and allows for a detailed and complex analysis; it is ideal for 'identifying, analysing and reporting pattern (themes) within data' and it provides organisation of the text followed by interpretation; it serves to reflect reality, and to unpick or unravel the surface of 'reality' (Boyatis,1998). It is an analytic approach widely used in research and, due to the fact that it has been incorporated into other forms of qualitative analysis, e.g. grounded theory, it has been described as being, 'a foundational method for qualitative analysis' (Smith, 2007, 2015); it can also be used as a method in its own right (Braun & Clarke, 2006), which is how it was employed in this research.

This method is not wed to any pre-existing theoretical framework and can therefore be used within many different theoretical frameworks and can be used to do different things within them (Braun & Clarke, 2006). The importance of transparency in terms of research epistemology was taken into account as this guides text reporting and informs what is theorised with regards to meaning. Thematic Analysis can be an essentialist or a realist method that reports experiences, meanings and the reality of participants, or it can be a constructionist method that interprets individual accounts

within a socio-cultural context (Braun & Clarke, 2006). The realist ontological position is the most widely used in psychological research (Wilkinson,2008), as a uni-directional relationship between meaning, experience and language is assumed (Widdicombe & Wooffitt, 1995). Taking this stance, it is possible to theorise about patient's personal ideas, opinions and understandings in a relatively straightforward way. As the exploratory nature of the research question was congruent with the realist theoretical framework the latter was adopted in this study.

The text comprised statements about the participants' experiences of TCMA and perceptions of benefits arising from the treatment and care provided at the clinic, in terms of health, wellness and QoL. The individual accounts were very diverse in style and length as illustrated by the examples in (appendix E). Analysis of the written commentaries took the form of Thematic analysis using the Braun & Clarke (2006) method.

Pre-analysis procedure. Consistent with the approach posited by Braun and Clarke (2006), a number of decisions were considered and made prior to the analysis commencing:

A thematic unit was considered to be an item of learning about the experience of patients who had undergone a course of acupuncture at the clinic.

A rich thematic description of the entire text was aimed for, rather than a detailed account of one particular aspect, in order for the reader to get a sense of the predominant and important themes.

Inductive, as opposed to theoretical, thematic analysis was aimed for. A process of coding the text without trying to fit it into a pre-existing coding frame or analytical preconceptions was adopted.

The aim was for themes to be identified at a semantic level, rather than latent level, i.e. the themes were identified within the explicit meanings of the text.
The analysis was dependent on the development of first codes and then themes; however, before this process is described it is important to clarify both of these terms. Codes were 'first-level' labels that were applied to sections of the text on the outcome questionnaires; the sections varied in length from a few words to several paragraphs, and each section could be coded as many times, with different codes, as was considered necessary. Some codes were created in vivo using the actual word or phrase in the text and some were created a priori, influenced by key issues that had arisen, e.g. in the literature review.

A theme captured something important about the text in relation to the research question and represented some level of patterned response or meaning within the text (Braun and Clarke (2006). Themes were identified using an inductive, bottom up, method; this was the most appropriate approach as it allowed for the themes to be driven by the text rather than the researcher using a pre-existing coding framework (Patton, 1990). Using this approach, the researcher captured what patients thought were the most important factors to impart and not what the researcher thought was important. There are typically two levels that exist in terms of theme identification; however, a thematic analysis usually focuses primarily on one level (Braun & Clarke, 2006). In this study the researcher focused on the explicit (semantic) level, i.e. themes were identified within the surface meanings of the text and nothing beyond what a patient had actually written. The alternative would have been to have examined the underlying meanings of the text, i.e. to have conducted an implicit or interpretive level of identification (Braun and Clarke, 2006), but as the aim in this research was to collect the views of patients with regards to their TCMA treatment the implicit level of analysis was not necessary; furthermore, the explicit level of theme identification was more in keeping with the pragmatic approach of the research. The analytic process involved progression from description, where the data was organised to show patterns in the semantic content, to summarisation and interpretation, where there was an attempt to theorise the themes and their meanings and implications in relation to the surrounding literature (Patton, 1990).

Stages of the analysis. The phases of thematic analysis used in this research are described in Table 2.6 (taken from Braun & Clarke, 2006)

Thematic Analysis Procedure

Braun and Clarke's thematic analysis guideline includes a multi-stage analytical procedure. The analytic process was an iterative and cyclical one involving a progression from description (where the data had been organised to show patterns in semantic content and summarised) to interpretation (where attempts were made to theorise the significance of the patterns and their broader meanings and implications). The first stage involved becoming familiar with the text, which was achieved by reading and re-reading it and making notes on initial ideas for codes. Stage two involved creating the initial codes for the text; parallel coding was employed, which permitted the same section of text to be classified into two or more codes, which in turn

maximised the amount of information that was derived from the text. Interesting features of the text were identified and relevant text for each code was pooled. The third stage of analysis involved searching for themes in the text, which involved combining codes together into potential themes and collecting relevant text for each theme; a hierarchical thematic structure was developed, i.e. themes and subthemes that were representative of the text. In the fourth stage the themes were reviewed to establish if they worked in relation to both the extracts that were coded and the text as a whole. The fifth stage required themes and subthemes to be named and defined (Table 2.6) and finally the reliability of the themes was checked.

Table 2.6: Phases of Thematic Analysis

Phase	Description of the process
1. Familiarising yourself with your data:	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking that the themes work (in relation to the coded extracts (level 1) and the entire data set (level 2)), generating a 'thematic map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells; generating clear definitions and names for each theme.
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

CHAPTER 3

This chapter presents the results for study 1, i.e. the results of the statistical analysis carried out to determine whether TCMA produced measurable improvement in Quality of life (QoL), and the findings from study 2, i.e. how patients experienced TCMA and their perceptions of the benefits, in terms of health, wellness and QoL, that arose from the treatment and care provided by the clinic.

Study 1: Results for the Quantitative Component of the Research

The Main Analysis

Treatment Outcome

Within subjects repeated measures ANOVA were employed to examine the effect of TCMA on QoL as measured by the MYMOP over a six-week course of treatment (Appendix F, p. 216).

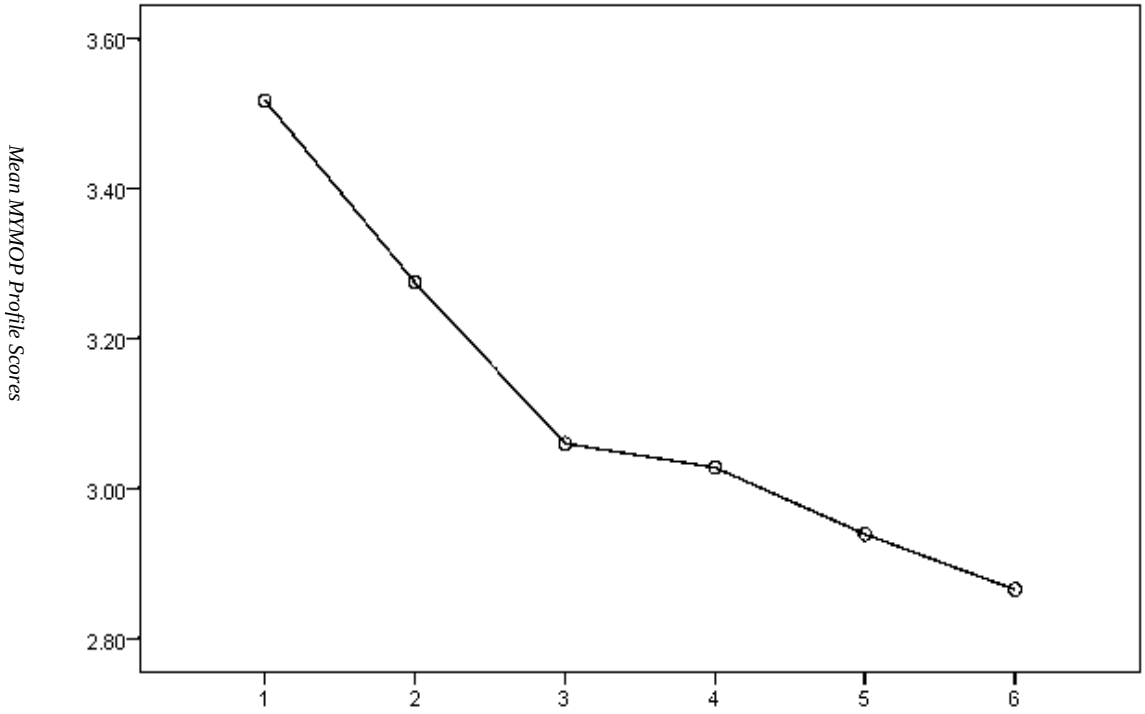
The mean MYMOP profile scores across time show a trend towards improvement i.e. from baseline assessment & treatment through to five follow-up treatments (treatment 6), see Figure 3.1.

Table 3.1 details the mean MYMOP profile scores for patients at baseline and across 5 follow-up TCMA treatments; MYMOP mean Profile scores are reported, together with standard deviations.

Mauchly's test indicated that the assumption of sphericity had been violated, $X^2(14) = 123.16$, $p < .001$, therefore degrees of freedom were corrected using Huynh-Feldt estimates of sphericity ($\varepsilon = 0.81$).

The within subjects repeated measures ANOVA results indicate that TCMA had a significant effect on QoL over time $F(4.0, 834.5) = 17.16$, $p < .001$. $\eta^2 = 0.08$. Significant differences were found in the direction of better reported QoL health status following TCMA.

This supports the hypothesis: A significant difference in QoL would be found between baseline assessment and outcome for TCMA patients over a course of treatment.



***Note*: 1 (Baseline (Treatment 1), 2 (Treatment 2) 3 (Treatment 3) 4 (Treatment 4) 5 (Treatmennt 6**

Figure 3.1: MYMOP profile scores across treatments

Table 3.1: Mean MYMOP Profile scores of patients over time (N=208)

Treatment	Mean	Standard Deviation
Baseline	3.5176	1.24386
FollowUp.1	3.2748	1.17711
FollowUp.2	3.0601	1.19972
FollowUp.3	3.0280	1.25404
FollowUp.4	2.9391	1.20588
FollowUp.5	2.8654	1.31806

Symptom Scores

Within Subjects Repeated Measures ANOVA was employed to examine the effect of TCMA on patient Symptoms over a 6-week course of treatment (Appendix G, p.220).

The mean MYMOP scores for Symptoms across time show a trend towards improvement i.e. from baseline assessment & treatment through to follow-up 5 (treatment 6).

Table 3.2 details the mean MYMOP scores for patients' Symptoms at baseline and across 5 follow-up TCMA treatments; MYMOP mean Symptom scores are reported, together with standard deviations.

Mauchly's test indicated that the assumption of sphericity had been violated, $X^2(14) = 110.09$, $p < .001$, therefore, degrees of freedom were corrected using Huynh-Feldt estimates of sphericity ($\varepsilon = 0.84$).

Significant differences were found in the direction of better reported MYMOP Symptom scores following TCMA, $F(4.2, 866.3) = 14.62$, $p<.001$, $\eta 2 = .07$

Table 3.2: Mean MYMOP Symptom scores of patients over time (N=208)

Treatment	Mean	Standard Deviation
Baseline	3.79	1.537
FollowUp.1	3.46	1.544
FollowUp.2	3.17	1.547
FollowUp.3	3.12	1.615
FollowUp.4	3.08	1.528
FollowUp.5	2.97	1.606

Wellbeing Scores

Within Subjects Repeated Measures ANOVA was employed to examine the effect of TCMA on patient Wellbeing over a 6-week course of treatment (Appendix H, p. 224).

The mean MYMOP scores for Wellbeing across time show a trend towards improvement i.e. from baseline assessment & treatment through to follow-up 5 (treatment 6).

Table 3.3 details the mean MYMOP scores for patients' Wellbeing at baseline and across 5 follow-up TCMA treatments; MYMOP mean Wellbeing scores are reported, together with standard deviations.

Mauchly's test indicated that the assumption of sphericity had been violated, $X^2(14) = 88.77$, $p < .001$, therefore degrees of freedom were corrected using Huynh-Feldt estimates of sphericity ($\varepsilon = 0.85$).

Significant differences were found in the direction of better reported MYMOP Wellbeing scores following TCMA, $F(4.3, 881.1) = 8.12$, $p<.001$. $\eta 2 = .04$

Table 3.3: Mean MYMOP Wellbeing scores of patients over time (N=208)

Treatment	Mean	Standard Deviation
Baseline	3.16	1.421
FollowUp.1	3.00	1.298
FollowUp.2	2.85	1.236
FollowUp.3	2.86	1.302
FollowUp.4	2.75	1.328
FollowUp.5	2.68	1.388

Activity Scores

Within Subjects Repeated Measures ANOVA was employed to examine the effect of TCMA on patient Activity over a 6-week course of treatment. (Appendix I, p. 228)

The mean MYMOP scores for Activities across time show a trend towards improvement i.e. from baseline assessment & treatment through to follow-up 5 (treatment 6).

Table 3.4 details the mean MYMOP scores for patients' Activities at baseline and across 5 follow-up TCMA treatments; MYMOP mean Activity scores are reported, together with standard deviations.

Mauchly's test indicated that the assumption of sphericity had been violated, $X^2(14) = 60.76$, $p < .001$, therefore degrees of freedom were corrected using Huynh-Feldt estimates of sphericity ($\varepsilon = 0.84$).

Significant differences were found in the direction of better reported MYMOP Activity scores following TCMA. F (4.2, 463.5) = 9.17, p<.001, η2 =.08

Table 3.4: Mean MYMOP Activity scores of patients over time (N=112)

Treatment	Mean	Standard Deviation
Baseline	3.80	1.702
FollowUp.1	3.47	1.588
FollowUp.2	3.30	1.676
FollowUp.3	3.18	1.532
FollowUp.4	2.93	1.686
FollowUp.5	2.94	1.767

Ancillary Analyses: Exploration of the Data

Analysis was completed to examine TCMA treatment outcome over time in relation to subgroups within the data (all values are reported as means ± SD). This was exploratory research, p values were based on two-tailed tests (all p>0.05), and Bonferroni adjustment was therefore not applied.

Gender. An Independent Samples t-test was conducted in order to examine whether treatment outcome was different according to gender; there was no significant difference, t(206) = .09, p = .93 QoL improved equally for both men and women over a course of TCMA treatment.

Age. A one-way ANOVA was conducted in order to examine whether treatment outcome was different according to age categories. There were no significant differences with regards to TCMA's impact on QoL in terms of the three age categories (Under 40 years, 40-59 years and 60+ years). TCMA impacted patients' QoL equally across all age categories over the course of treatment.

A bar graph representing the means and accompanying error bars representing the confidence intervals are shown in Figure 3.2. From the graph depicted it appears that there was a significant difference in baseline assessment MYMOP profile scores of patients treated with TCMA in the age category Under 40yrs and the age category

40-59yrs. The 40-59 yrs. age category had lower mean MYMOP scores at baseline, treatment 1 (mean 3.24) than the Under 40yrs category (mean 3.80).

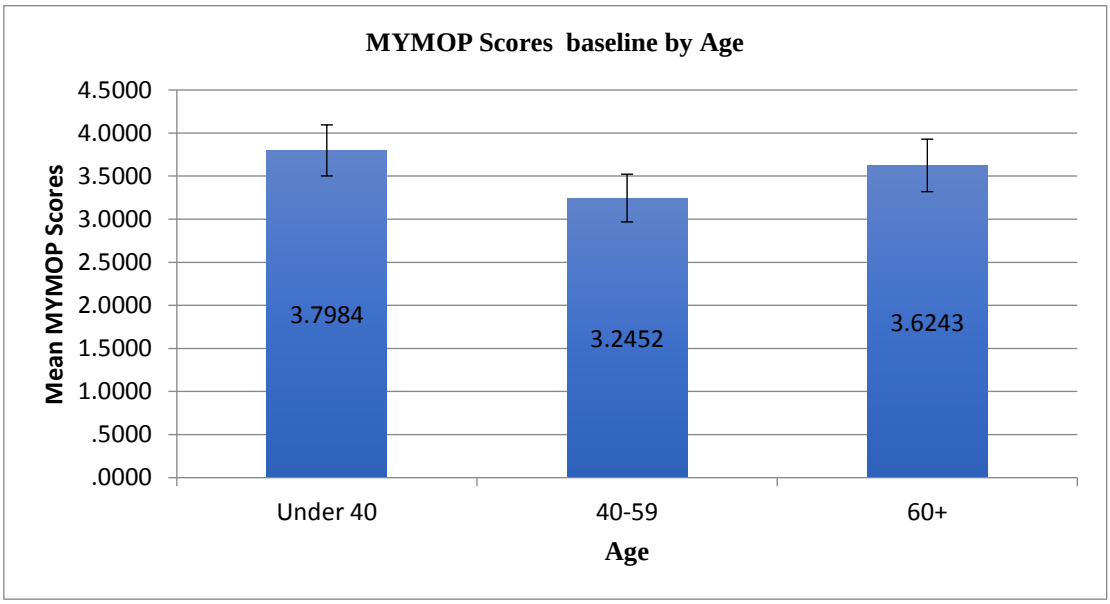


Figure 3.2: MYMOP scores baseline by Age

A bar graph representing the means and accompanying error bars representing the confidence intervals are shown in Figure 3.3. From the graph depicted it appears that the Mean MYMOP scores of the patients treated with TCMA aged 40 to 59 years and the Under 40 years category were significantly different at outcome (follow-up 5, treatment 6). In correspondence to their lower baseline (treatment 1) scores, the 40 to 59 years age category had lower mean MYMOP profile scores at treatment outcome, follow-up 5, (treatment 6) (mean 2.58) than those within the under 40yrs age category (mean 3.30).

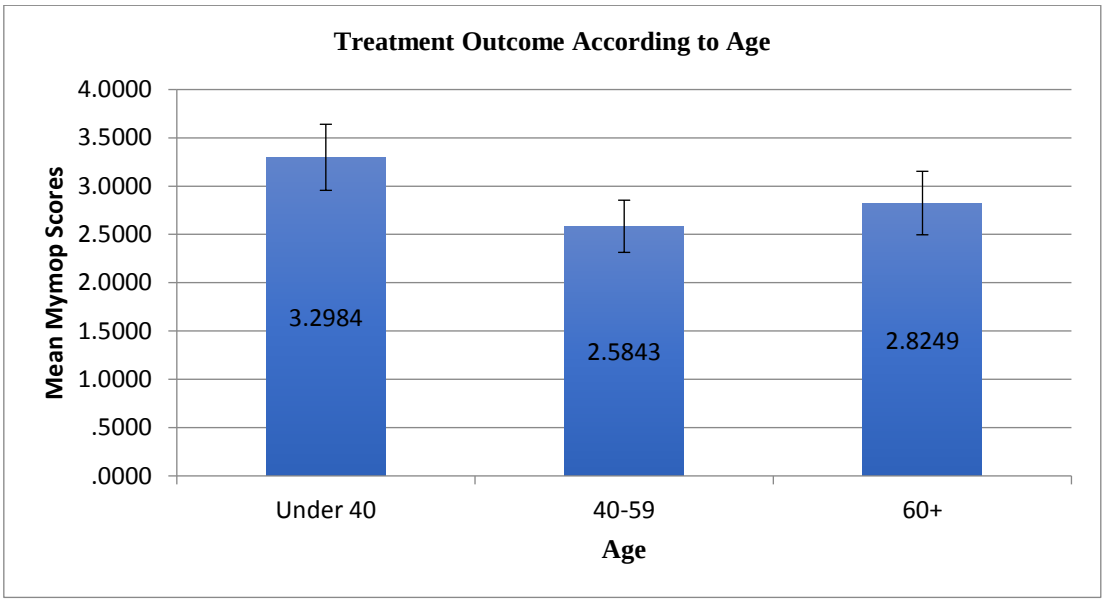


Figure 3.3 Treatment outcome according to age

Ethnicity. An independent samples t-test was conducted in order to examine whether treatment outcome was different according to ethnicity; there was no significant difference, t(206) = .45, p = .65, QoL improved equally for all ethnic groups over a six-week treatment period.

Social grade. An independent samples t-test was conducted in order to examine whether treatment outcome was different according to Social Grade. There was no significant difference, t(206) = -.783, p = .435, QoL improved equally for Social Grade categories ABC1 and C2DE over the course of TCMA treatment.

Symptom categories. A one-way ANOVA was conducted in order to examine whether treatment outcome was different in relation to symptom categories. There were no significant differences with regards to TCMA's impact on QoL in terms of the Symptom Categories (Musculoskeletal, Psychosocial and Other). TCMA impacted patients' QoL equally across all symptom categories over the course of treatment.

A bar graph representing the means and accompanying error bars representing the confidence intervals are shown in Figure 3.4. From the graph depicted it appears that there was a significant difference in baseline assessment MYMOP profile scores of patients treated with TCMA in the Musculoskeletal symptom group in comparison to both the Psychosocial and Other symptom categories. The Musculoskeletal symptom category had higher MYMOP profile scores at baseline, (treatment 1) (mean 4.10) in

comparison to those in the psychosocial symptom category (mean 3.32) and the Other symptom category (mean 2.88).

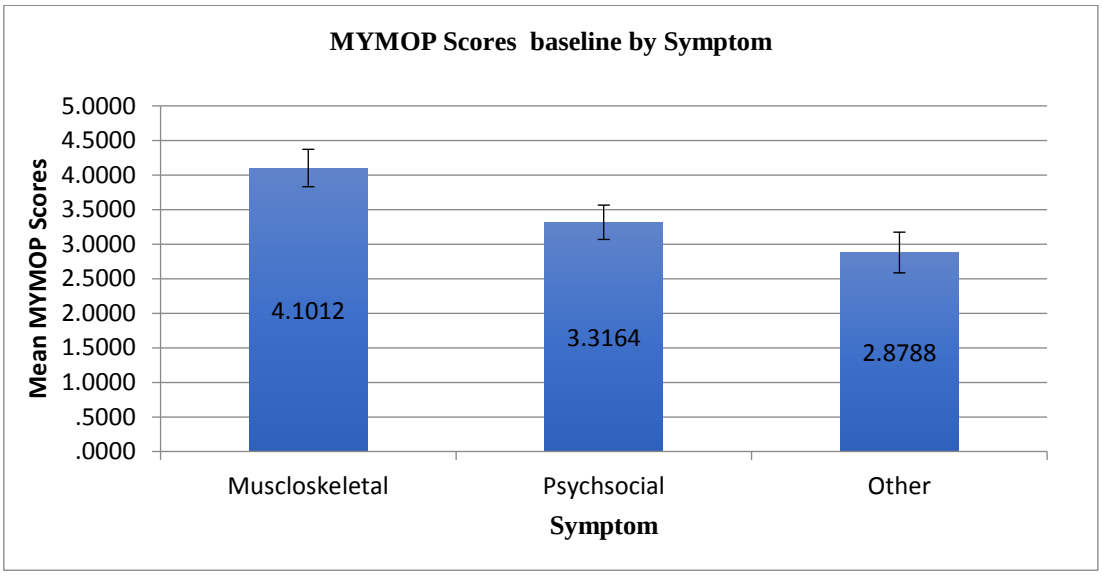


Figure 3.4: MYMOP Scores baseline by Symptom

A bar graph representing the means and accompanying error bars representing the confidence intervals are shown in Figure 3.5. From the graph depicted it appears that the mean MYMOP scores of the patients treated with TCMA in the Musculoskeletal symptom group and the Psychosocial and Other categories significantly differ at outcome, follow-up 5 (treatment 6). In correspondence to the Musculoskeletal categories groups' higher baseline treatment 1 scores, the Musculoskeletal symptom category had higher mean MYMOP profile scores at treatment outcome, follow-up 5, (treatment 6) (mean 3.43) than those in the Psychosocial category (mean 2.87) and 'Other' category (mean 1.99).

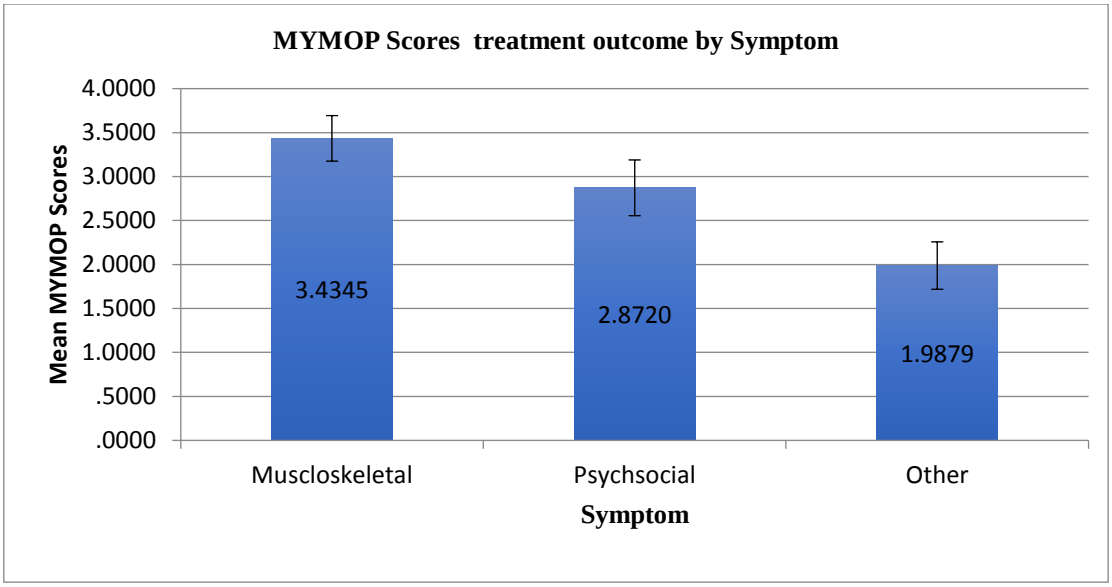


Figure 3.5: MYMOP Scores treatment outcome by Symptom

Study 2: Findings from the Qualitative Component of the Research

Main Themes

The following five key themes were identified within the narrative text: Healing Nucleus; Influences on Main Complaint; Burgeoning Effects; Wellbeing and Quality of Life; and, Agency (Table 3.5). This section explores these themes in relation to patients' experiences of acupuncture treatment.

Table 3.5: Table of Themes

Theme 1: Healing Nucleus
Subtheme 1: Traditional Chinese Medicine Acupuncture (TCMA) assimilated
Subtheme 2: Practitioner (and environmental) attributes
Theme 2: Influences on Main Complaint
Subtheme 1: Improved function: emotional, cognitive and physical domains
Subtheme 2: TCMA treatment as ineffective or achieving limited effects
Subtheme 3: Treatment efficacy as a process
Theme 3: Burgeoning Effects
Subtheme 1: Outlook
Subtheme 2: The changing Self
Subtheme 3: Coping and resilience mechanisms
Theme 4: Wellbeing and Quality of Life (QoL)
Subtheme 1: Practical tangible benefits for an enhanced QoL
Subtheme 2: Harmony
Theme 5: Agency
Subtheme 1: Command over health and healthcare
Subtheme 2: Self-agency towards health

Theme One: Healing Nucleus

Healing nucleus, was the energetic space that facilitated health and healing and was representative of the contextual framework within which healing and improved health were made achievable and realised. Healing was deemed to be more than the sum of its component parts as narratives detailed miscellaneous treatment ingredients that

worked together synergistically, creating a complex dynamic system in which each component built on, and interacted with, the contribution of the other components. Narrative text depicted the complexity of the various components that were present in the act of treatment and detailed the 'non-specific' and 'non-technical' aspects of treatment that were specifiable and deemed central to healing. As well as clearly expressing a belief that the treatment process as a whole was beneficial, patient narratives mentioned the separate components of treatment, i.e. techniques, theory, practical action, and the therapeutic relationship as a complex whole, as being contributory factors in the facilitation of health and healing.

Healing nucleus had two subthemes. The first, 'TCMA assimilated' was concerned with how patients related to, understood and assimilated TCMA which was evident in, and discerned from, patient narratives that demonstrated such understanding; this theme incorporated how patients learnt and assimilated their knowledge and understanding of TCMA as well as how they related to and used it. The patient narratives from which this theme emerged contained vocabulary that described basic TCMA principles; furthermore, those narratives were imbued with holistic ideology and described TCMA's influences and values as well as its diagnostic approach. Patients explicitly referred to the benefits of 'whole person' treatment effects, including physical, emotional and social components; they also commented on their affinity with the treatment and the value of its approach, i.e. how it promoted patient education towards self-efficacy via the therapeutic relationship.

The second subtheme, 'Practitioner and environmental attributes', was concerned with the psychological processes that accompanied treatment administration. It looked at the personal disposition of the TCMA practitioners and environmental attributes that rendered healing and highlighted aspects of the treatment (healing encounter) that patients deemed to be at the heart of their healthcare. Patients mentioned the skilled practitioner in terms of diagnostic and needling skills and also heavily emphasised the centrality of the therapeutic relationship. Narratives described valued aspects of the process of care such as being recognised, feeling heard, being supported, touched, mutuality, trust, safety, experiencing empathy and enablement and how new meanings were made. Many patients lamented how these key experiential features of TCMA were absent in western medical care.

Subtheme 1: Traditional Chinese Medicine Acupuncture (TCMA) assimilated.

This sub-theme was about how patients understood, related to and assimilated TCMA. As treatment was based within a TCMA framework, 'Eastern Philosophy' significantly impacted on treatment procedures and outcomes, which unsurprisingly resulted in patient narratives being rich in the vocabulary associated with that philosophy. For example, TCMA theory expounds that basic energy supports all life matter and some patients used these terms, 'basic energy' and 'life matter' (as well as other typical TCMA concept descriptors) when they described events such as treatment sensations or 'energetic' experiences.

It was clear from what patients wrote, that the eastern framework (and associated vocabulary) within which TCMA operates had a significant influence on their perceptions of both treatment and outcomes. Patient narratives included self-reflection, using TCMA energy theory metaphors, in somatic experiential terms regarding personal energetic states both before and after treatment. In place of common Western 'medical' terms such as depression or melancholy patients used vocabulary that a TCMA practitioner would use. For example, TCMA practitioners commonly refer to 'Qi' and to energy being 'stagnant' and they often describe a particular energetic situation as being 'stuck', and narrative text collected in this study contained many examples of how patients adopted this terminology and the philosophical framework of TCMA and included the following:

> *"…I see my acupuncture treatment as a balancing force balancing the yin and the yang I was out of balance (…) acupuncture always does the trick and shifts things a few notches … I feel absolutely wonderful…" (Patient 18)*

There were also the more pragmatic textual narratives, i.e. where descriptions of what happened in the treatment room, as well as basic TCM principles, values and diagnostic approach had been assimilated and incorporated within the textual responses. For example, a patient shared the following:

> *"…I love that everything is checked, the pulses of the organs and your tongue colour … everything shows what's going on inside… the dampness in my spleen that was causing my bloating went away…and acupuncture increased circulation and everything related to my lungs, kidneys and heart….and you can feel the sensation,*

an energy and heat and calmness when you are having treatment. She really has got healing hands!" (Patient112)

TCMA maintains that all phenomena, all form and substance in the universe, is the materialisation of energy. Thus, individuals exist as an integral part of that energy-filled universe and within this world view the mind, the body and the spirit are merely different manifestations of the same life force that cannot be considered separately. It advocates ideas of one unbroken wholeness and universal connection where the focus is on the complete physiological and psychological individual in his or her social environment (family, culture, ecology), and where health problems are understood and treated in relation to that whole. This holistic personal approach, which is integral to TCMA, was cited as beneficial and impactful by the majority of patients.

Narrative texts incorporated eastern ideas of the self and the unique self; patients referred to the importance of including the body, soul and spirit of a person in treatment and they articulated their beliefs that caring for the human spirit was just as important as caring for the physical body. This and other perceptions of the key components in successful treatment regimens, that are central to TCMA but largely alien in Western medicine, emerged in many of the patient narratives. Patients described their experiences using either the term 'holistic' itself or other terms that were recognisably equivalent to it. Examples included:

"It was so lovely to have the acupuncturist work with you as a whole system I appreciated that (…) he sees me as a whole person (…) it's really a mind body integrated approach (…) acupuncture feels balancing I felt like my whole being and my soul were being looked after as well (….) mental, emotional physical is being touched (…) they didn't leave anything out (…)" (Patient 90)

The holistic approach was associated with patient experience of a more natural approach to healthcare and one that had fewer side effects, as illustrated by the following comment:

"(…) I believe acupuncture is vital to mental emotional and physical wellbeing compared to pharmaceutical drugs (…) I got better without the side-effects…a more holistic approach (…) thank you from the bottom of my heart." (Patient 29)

At the centre of oriental medicine is the belief that, "man helps, and nature cures', and accordingly, TCMA practitioners, in treating the "whole", offer patient education towards self-efficacy, which is achieved via the therapeutic relationship. There was a sense from the text that most patients appreciated the focus on the self and the

promotion of self-healing, self-care practices and disease prevention that is so integral to this holistic approach. Patients experienced hope, reassurance, encouragement and explanation about their conditions leading them to understand their health problems differently. It was clear that patients who offered this narrative were fully engaged in their treatment and participated fully in their own care. Patients welcomed the full range of knowledge and skills utilised for their benefit and felt that the advice that they had been given, for example lifestyle advice that included special diets or exercises, enabled them to help themselves, and that this contributed to their recovery. Illustrations included:

> *"(…) I like to help myself wherever possible and coming for acupuncture treatment really put me on the road to recovery… It was good I got advice on what might make my problem worse or what might help and to help know what the best diet was based on my personal eating practices my social practices etc. and in controlling my pains and avoiding such things in the future (…)." (Patient 45)*

> *"(…) (Name) expert advice is wonderful. I appreciate all she gives me educationally she always has new information to give me and new reading materials (…) (Name) knows what to say to me it's logical and she puts an understandable framework around things (…) she encourages me and I have made lots of lifestyle changes dietary things, exercise, coffee, alcohol (…) coming for acupuncture treatment has strongly influenced the positive change in my health (…) I believe that this approach leads to a lifetime of self-care. Thank you." (Patient 54)*

Patient narratives indicated that they enjoyed and valued the participation and discussions that led to a shared perspective and the sharing of knowledge and power. Patient statements suggested that their perception of their treatment was one of practitioner and patient engaged in an egalitarian relationship; a mutual endeavour of grasping problems and working in partnership to alleviate them. Examples illustrating this included:

> *"(…) I was given a satisfactory explanation of my condition, support and understanding (name) showed real interest in my problem (…) so we can work together on the improvement of my health (…)" (Patient 92)*

> *"(…) I like my acupuncturist very much…In acupuncture you are being part of the whole process (…) It's a partnership and I'm not passive in this (…) it makes me feel good that I do my bit too." (Patient 94)*

Many patients expressed some dissatisfaction with Western Medicine, and many other patients made direct comparisons between it and TCMA, with the former being consistently criticised for failing to provide the individual care and attention characteristic of TCMA, examples included:

"(…) none of the usual medical people no one, my doctor and hospital wanted to help me and then I came here (...) they talk to me and understand my problem and they care. This is nowhere else so I love this treatment (…) my hand is too tired to write more but good things!" (Patient 89)

Subtheme 2: practitioner (and environmental) attributes. The practitioner and environmental attributes sub-theme incorporated the personal disposition of the acupuncture practitioners and the environmental factors that promoted healing; this subtheme highlighted the healing encounter that patients perceived to be at the heart of their healthcare. Perceptions of practitioner characteristics in relation to the personal holistic approach were prevalent within the narrative texts. Words used by patients included 'kindness', `holistic approach', 'friendly' and 'compassionate'. Patients were appreciative of how their treatment was delivered; the empathy and understanding as well as the time, attention and personal interest shown in them by practitioners, which was referenced in a significant proportion of the patient narratives. That the personal holistic approach succeeded in creating a positive therapeutic relationship within which patients felt valued and supported was also evident in the many comparative discourses of GP traditional western versus holistic approaches to healing. What was perceived by patients as positive personal dispositions of their acupuncture practitioners was evidently an important contributory factor in a satisfactory consultation and was a determining factor in improving patient health and wellbeing. Illustrations included:

"(…) There was no room for emotional chat in my GP's appointment time (…) I'm very satisfied with the acupuncturist and the treatment, he takes great interest in me as a person and asks me questions and we'd talk (…) I would always feel better after the treatment and really benefited from the time given to help me through emotional as well as physical feelings (…)." (Patient 84)

" (...) I appreciated a full consultation with a practitioner (…) a less hurried approach to my condition was wonderful. (Name) spent endless time with me trying to help with problems whereas the medics attitude is learn to live with it." (Patient 109)

Narratives concerning the personal holistic approach included the words 'kind' and 'caring' in relation to practitioner attributes, for example:

"I believe that I was treated with great kindness and understanding by (name), a beautiful person so tender and caring (...) and I feel so much better now so it really worked and I would recommend it to anybody." (Patient 12)

As well as praising the friendly and impactful personal attributes of all staff at the TCMA clinic, patient comments also referred to the importance of the treatment centre's therapeutic influence. Comments regarding the treatment environment being a therapeutic one that contributed to feelings of wellness included:

" (...) Great environment too! Service, staff were very friendly and sympathetic. I don't know where I'd be without this place. Everyone needs a service like this where people care about you, from the moment you go in to the moment you walk out the kind treatment continues to be there with you." (Patient 102)

Patients described experiencing a supportive framework of mutual trust, respect and care; many referred explicitly to trusting their practitioners and regarded it to be an important factor contributing to their successful treatment outcomes, examples included:

"The care and the attention I received during my visits for treatment have been top class and I have been treated with great respect. I have felt at ease with (name) and I respect his professionalism (...)." (Patient 107)

Patients referred to 'authentic' relationships where they experienced a high level of acceptance and empathy from practitioners. In their comments, many highlighted the importance of being treated as individuals with their own experiences and stories to tell, one patient articulated this experience by declaring that what made the difference and created a positive effect was being listened to, 'as someone who mattered and as someone whose story was significant'. Being treated as though their life and troubles were worth attending to and having those personal individual issues addressed in a serious and respectful way resulted in patients feeling acknowledged and validated, examples included:

"(...) (name) is superb and he has a wonderful approach. I talk to him on a one to one basis and he understands and I always feel more confident and comfortable afterwards (...) he puts me at ease and gives me a more realistic perspective and it is comforting (...) I come out feeling like a burden has been lifted and that things are not so bad (...)." (Patient 14)

Theme two: Influences on Main Complaint

Theme two, *influences on main complaint*, incorporated narratives of patients making sense of TCMA's impact on their main complaint. The theme incorporated their beliefs about treatment effects and the functioning of TCMA, i.e. the meaning of the treatment to patients in practical terms, patient satisfaction, and expectations of outcome with regards to the main complaint. Patients described, evaluated and reported on the many different and intersecting ways in which TCMA produced its effects (or failed to). Narratives detailed information regarding the intervention characteristics with regards to how, for whom and under what circumstances TCMA might have worked. Reflections on the perceived effects of TCMA treatment on symptoms were organised into the three sub-themes reflected in the data.

The first sub-theme, 'Improved function: emotional, cognitive and physical domains', concerned patient perceptions of TCMA's influence over health issues within those three named domains. The second sub-theme, 'TCMA treatment as ineffective or achieving limited effects', represented narratives pertaining to patient dissatisfaction with treatment and/or treatment limitations in terms of influencing symptoms. The third sub-theme, Treatment efficacy as a process, concerned patient experience of TCMA treatment effectiveness analogous to a complex non-linear journey.

Subtheme 1: Improved function: emotional, cognitive and physical domains. TCM theorises that an imbalance of energy may show itself as either a disturbance in the highest functions, or a disturbance in the so-called lower functions, or both, and patient narratives could be classified according to these categories. Patient narratives conveyed the impression that treatment operated on a physical level (i.e. one corresponding to those parts that could be seen, touched, and/or perceived with the physical senses), on an emotional level (i.e. to do with feeling, emotion or affect) and on a mental level (i.e. to do with thought and perception-cognition). Many narratives mentioned symptoms in relationship to, 'limitation of function' and of TCMA in relation to 'freedom from limitation of function' and the impact that 'freedom from limitation of function' had on their lives.

Mental functioning. TCMA had an effect on patients' mental energy, i.e. the vitality and liveliness of the mind, and treatment increased levels of mental activity in terms of memory, concentration, abstract thinking and communication. Patient narratives described the effect of TCMA on mental clarity and identified its positive impact on the ability to think clearly; one patient referred to its effect on clarity of

thought as, *'clearing the fog'* (patient 104). Patients also described a positive impact that TCMA had on attention, i.e. the ability to focus, concentrate or absorb things, as well as improved memory functioning and better decision-making abilities. Illustrative examples included:

> *"(…) with having ADHD I was constantly shifting from one thing to another and could not attend to anything, I was restless and fidgety and couldn't concentrate or focus well (…) I was distracted easily, constantly on the go (…) I am much better now with this (…) I used to have great difficulty organizing and completing tasks now my studies have improved tenfold (…)." (Patient 117)*

Emotional functioning. Many patients referred to TCMA as releasing emotional pain and positively impacting the symptoms of, and providing relief from, emotional disorders. Illustrative examples included:

> *"Acupuncture improved my life in a psychological way, emotionally (…) it took a few treatments and there were lapses when I'd feel low but the depression has lifted now (…)." (Patient 25)*

> *"This has made a huge impact on my life for the better. I have found the results of my treatment to be profound and amazing, for years I've tried to deal with depression and anxiety with antidepressants and therapy which made me feel worse, suicidal. I would recommend acupuncture treatment to anyone without it I don't think I could function and would have felt bad about myself for years to come maybe I would even be in my grave (…)." (Patient 44)*

Physical functioning. In addition to emotional pain, patients also commented on the positive impact that TCMA treatment had on painful conditions; frequent references to its impact on physical symptoms, including musculoskeletal conditions, were made and suggested that TCMA provided both relief from symptoms and improved function, illustrative examples included:

> *"(…) which got to be quite immobile I'm impressed with (names) skills (…) I have tried GP's, physio's, osteopaths etc. He pinpointed the exact problem and mobility is back in both shoulders (…) I am so grateful and feel lucky to have found*

acupuncture (…) before this treatment I was like a bear with a sore head. Thank you so much." (Patient 22)

"Before coming here, I was in constant pain and there are a lot of things I couldn't do. Since coming here, I've not been in constant pain and I've done more than I did before (…) all in all 10/10." (Patient 77)

Patients described how TCMA provided relief from symptoms of various complaints, and included in their commentaries was information regarding improved functioning in many different areas of behaviour due to treatment:

"(…) definitely benefitted from this acupuncture after treatment one a lot less numbness and tingling in the toes and in my legs (…) It got better and better every treatment a bit better. I have relief of the pressure I work in shop all day standing causing problems for me heavy and aching and veins sometime get lumps and itch with bleeding (…) I feel much happier with it and more comfortable and stand for longer in the shop." (Patient 6)

"(…) suffer with a stitching pain in my stomach sometimes a continuous throbbing on the right side and I found it hard to go to the toilet at times and I could be very constipated or be continuously running to the toilet (…) my stomach looked 9 months pregnant and I had stopped going anywhere social unless unavoidable (…) since acupuncture I'm feeling a lot better and I'm indebted to (name) I can now go to the toilet regularly and normally, and I'm less stressed and have more of a social life my stomach pain has also subsided so I'm happier (…)."(Patient 13)

Subtheme 2: TCMA treatment as ineffective or achieving limited effects.

Although most patients reported benefits and positive effects of their treatments a small minority perceived that the treatment was either ineffective or of only short-term benefit. Narratives from these patients described experiences of general dissatisfaction with their treatment but, paradoxically, many of these narratives also included references to gaining some benefit from the treatment; i.e. in spite of the expressed general dissatisfaction with treatment outcomes these patients considered that acupuncture had made positive contributions to their health. Such narratives illustrated the complexity in how treatment effects were experienced and sustained over time. Furthermore, many narratives that detailed dissatisfaction alluded to a desire to continue acupuncture treatment for as long as possible.

A few patients who had chronic conditions were cautiously optimistic about treatment effects and expressed dissatisfaction with what they perceived as a failure to provide a sufficient amount of TCMA; they commented on their course of treatment being inadequate in terms of the number of sessions they were given, i.e. the six-session clinic protocol, and they therefore deemed treatment effects to be limited. The

perception of these patients appeared to be that acupuncture treatment was beneficial, but that for lasting long term positive outcomes, the treatment needed to be regular and ongoing, for example:

> *"My knee pain is easier but still really stiff, for my elbows it hasn't worked (…) maybe my case is too much and too chronic (…) unless its possible to have more regular treatment for a longer time than this (…)". (Patient 79)*

A small number of patients described the benefits of their TCMA treatment as short-lived with symptoms returning quickly, illustrations included:

> *"(…) I definitely benefited (…) but the symptoms quickly return in between treatment." (Patient 42)*

> *"(…) It only eases the pain for a couple of days after treatment the pain always returns (…)." (Patient 51)*

Other patients had the perception that ongoing 'booster' TCMA treatments were required, as illustrated by the following comments:

> *"Fantastic, thank you, incredible (…) Since my car accident and the removal of my spleen, and you working on the spleen, the nerve ends of the spleen and after the second treatment the symptoms gone! (…) the only way I can see that continuing is to get a booster every 2 weeks or every 4 weeks….more please!" (Patient 65)*

> *"I have found acupuncture a great source of relief for many symptoms over the years. Whenever I have it life dramatically improves. I would much prefer this course of treatment rather than taking a multitude of medications. This treatment is very effective for all my past and present ailments and I will always come for booster sessions to keep me going." (Patient 115)*

For those few patients that found TCMA to be ineffective with regard to their main complaint, illustrations included one patient who found the treatment to be ineffectual on the progression of symptoms and complained, *"I'm feeling no better – just worse!"* (Patient 35)

Such narratives detailed patient understanding of the intervention's effects and optimisation of services with regards to improving healthcare delivery and further highlighted crucial patient perspectives with regard to understanding intervention effects in relation to the context and process and the optimisation of TCMA healthcare.

Subtheme 3: treatment efficacy as a process. Patient narratives described TCMA's impact on chronic health conditions as being more of an improvement 'process' than a cure, i.e. symptoms were still present following treatment, but they

were improved, and they followed a process of important, noticeable improvements, over time, (e.g. weekly), some patients described experiencing decreases in frequency, intensity and/or duration of their symptoms post treatment. Furthermore, some patients described the healing process as involving a temporary heightening of physical and or emotional problems as energetic layers of imbalance were cleared away. According to TCMA, symptoms appear and disappear in reverse order of their appearance in the body, thus a patient may re-experience symptoms of a previous illness during the healing process of a presenting illness, or the presenting illness may temporarily worsen in the course of treatment; although this is unpleasant it is deemed a necessary part of the healing process and it typically resolves quickly (Kaptchuk, 2014). These aspects of treatment were reflected in patient narratives with some explicitly stating that their symptoms had, during treatment, got worse before they got better, for example:

> *"(...) there was a lot of pain, heat and stiffness in my right hip and pain across the top of both feet and in my right ankle from arthritis (...) acupuncture worked for me within one month for my hip that was fine and pain free and my ankle settled but my feet got worse becoming more and more uncomfortable (...) then after a few treatments the pain shifted a bit further down the feet and then it all settled (...) and I've actually attended a dance class again (...). I would like to thank (name)." (Patient 89)*

Other patients reported slow but nevertheless positive progress with ultimate benefits, as illustrated by the following comments:

> *"The treatment and centre are superb. Since attending here I've found nothing but steady ongoing improvement for many complaints that have been with me for many, many years. My first treatments it made the pain go away part of the time and then every time it staved off the pain more and more for longer amounts of time. I know that I am soon to be pain free." (Patient 64)*

> *"(...) I've had migraine headaches for many years. I have high blood pressure and very high amounts of stress in my life. Since acupuncture bit by bit the pain has become less frequent, less intense and now I will rarely ever get one (...) she is wonderful!" (Patient 32)*

Patients who were not necessarily 'cured' of their symptoms, i.e. their symptoms were not completely relieved, sometimes included in their comments an implicit acknowledgement of this, but still reported noticeable and important improvements and clearly felt that the relief they achieved was beneficial, for example:

"I have felt improvement with the severe pain that I have had with my period pain which has been with me since a teenager and I've got my life back (…) I was wiped out for a full week with it every month and would miss a week of my life (…) the treatment has been fantastic because although I still have some cramps my period has evened out and I haven't had to take neurophen as much and I used to take 8 a day plus 4 paracetamol (…) so I'm without the side-effects of drowsiness that I felt on that pill combination (…)" (Patient 71)

"A good result. The pain and stiffness in my toes from the neuropathy has been reduced and it is controlled to a tolerable level some cramping remains though much better generally (…) I suffer with arthritis in my shoulder and hips and though the pain is still there it prevents the unrelenting pain and it used to be worse in these winter months, but this treatment is absolutely marvelous." (Patient 43)

Theme Three: Burgeoning Effects

Burgeoning effects was concerned with positive outcomes of TCMA that were neither directly related to the presenting complaint(s) nor an intentional primary objective of the treatment. This theme highlighted TCMAs' influence in terms of facilitating patients' growth and development in unexpected areas, which was illustrated by one patient who noted:

"(…) most of my year long sufferrings have been cured. This makes me more assertive (…)" (Patient 93)

TCM is presented in the literature as a holistic medical system with a coherent philosophy that integrates many, possibly all, aspects of human life. It is typically described as a comprehensive approach to healing that goes beyond simply treating physical health complaints, i.e. a medical intervention that achieves positive clinical outcomes and, at the same time, improves overall patient well-being. TCM considers that everything in the universe is a different manifestation of the same life force; nothing can be considered separately, and the entire range of human behaviour, personality and intention is in the province of energetics, or in TCM terminology, the 'Qi'. A tenet of TCM is that rigidities on the level of the psyche externalise to corresponding rigidities on the level of the soma and treating one will therefore necessarily impact the other (Beinfield and Korngold, 2013). In the context of TCM 'burgeoning effects' are a predictable outcome of TCMA.

Burgeoning effects had three sub-themes: 'outlook', which was concerned with changes in the patients' perceptions of the way the world is, i.e. changes in their world-view; 'changing self', which was concerned with changes in patient self-perception and

the self-awareness that they attributed to TCMA; and 'coping & resilience mechanisms', which was concerned with the impact of TCMA on the patients' ability to cope with the demands of daily living.

Subtheme 1: outlook (world view). Relevant patient commentaries employed comparative language that described shifts in beliefs, attitudes, and perceptions pre and post-treatment, as well as the ramifications of those cognitive changes on their lives. Many patients detailed wide ranging, positive changes in their habits, attitudes, perceptions and perspectives on life and living generally, as illustrated by the following comments:

> *"(…) new hope now a light at the end of the tunnel they have shown me (…) life can be looked at from a new angle now and the only way is up (…) it has changed my life (…)." (Patient 25)*

> *"(…) After treatment the world is the same but you view it differently (…) acupuncture has given me a mentally clarity and allowed me to view the circumstances in my life with… more objectivity, It almost gives you the possibility to go outside yourself and look at things from an external point of view (…)." (Patient 16)*

Subtheme 2: the changing self. Some patients described having experienced changes in their personality and improved relationships with themselves, the latter was frequently articulated as some form of transition process, fuelled by the treatment, that involved lost parts of the self being found. The concept of a healthy self being re-established, and the resulting impact of this change were also part of this subtheme.

In many patients TCMA appeared to have precipitated a shift in their sense of 'self'; an experience that was described by many patients as a personal inner journey from an 'old' self-identity to a 'new' one, which were typified by comments such as: *"feeling like a new person."* (Patient 28) and *"a new human."* (Patient 41). Some described experiencing a sense of having achieved a 'healthy self', as illustrated by the following comments:

> *"(…) my family say I'm back to myself again after 10 years (…) acupuncture has given me back my wellbeing feeling" (Patient 91)*

> *"(…) It's an inspiration to my whole life. When I first came I was shy, nervous, full of anxiety, blood pressure, pain etc etc it has taken me back to a normal way of life." (Patient 12)*

Comments also suggested that for some patients the treatment increased self-regulation and self-awareness of personal identity, positive feelings towards the wider world generally, and personal responsibility for health, examples of such comments included:

> *"(…) I have begun to have a strong interest in my health (…)." (Patient 63)*

> *"(…) for me this has been an essential part of me having a positive attitude and actions towards my health and wellbeing both physically and mentally (…)." (Patient 96)*

These profound changes in self-perceptions might have allowed patients to see the link between their behaviours and the consequences of those behaviours and how they could, by making corrective adjustments to the former, improve both their physical health and their psychological well-being, which was evident from the following comments:

> *"(…) I was someone who drank heavily and had the odd drug or two. The craving for alcohol has completely disappeared. I no longer get depressed and I don't take anything (…)." (Patient 68)*

> *"(…) I am much more confident and self-assured than I was at the start of treatment, I have gained a courage of my convictions to change certain aspects of my life which I wouldn't have done before and now I constantly change stuff that isn't good for me mentally or physically– in my job (…) a complete turnaround since treatment, I handle everything differently everything is better there (…)." (Patient 116)*

Some patients described very clearly and explicitly how they experienced TCMA as a tool that 'opened them up' to new feelings, thoughts and behaviours; many described evolutionary developments in relationships and changes in personal experiences of the self, which strongly suggested that significant personal growth and transformation had taken place, illustrations included:

> *"(…) I was very low but now I feel like I'm on cloud nine! I have never experienced so much movement in such a short space of time, not even in my 10 years of counselling and psychotherapy (…)" (Patient 111)*

There was evidence that TCMA was a catalyst for personal transformation; a force responsible for integrating and embedding within the patients psyche new ideas related to how the individual could, consciously and unconsciously, change and correct damaging behaviours (Hammer, 1991). Treatment was credited with producing an integration of insight and understanding, as well as a strengthening of self-discipline;

patients perceived treatment as responsible for creating the inner strength required to face life and to change themselves and the conditions of their existence, which was lucidly expressed in the following patient observations:

> *"(…) acupuncture seemed to be the vehicle by which this inner knowledge is integrated within me, almost immediately I felt changes happening (…)". (Patient 27)*

> *"(…) Acupuncture treatment makes me more aware (…) it's like a positive energy building and I'm increasingly inclined to take the steps that are needed to care of myself and bit by bit I'm doing more to help myself. I believe its set me up for a lifetime of self-care (…)." (Patient 75)*

Significant personal change was a commonly reported outcome of TCMA treatment, including: more connection with mind and spirit; more confidence and conviction regarding life choices; and feelings of empowerment regarding decision making. As discussed above, in relation to the 'holistic environment' theme, patients emphasised the importance of the process of engagement with their TCMA practitioner in determining these positive experiences and they described how the therapeutic relationship was instrumental in promoting positive growth-enhancing interactions. This was referred to specifically in relation to the way that relationship promoted an awareness of personal needs and requirements in relation to self-care, as illustrated by the following comments:

> *"(…) acupuncture treatment reminds me when I am taking poor care of myself (…)." (Patient 60).*

Treatment was identified as having empowered patients by giving them permission to engage in and focus on their own self-care needs, which contributed significantly to the healing process. For example, some patients described how they became aware of a need to create time and space in their lives to address their own well-being issues; others described how they needed to slow down and take 'time-out' for their own health and development needs. Many patients perceived TCMA treatment and the 'healing environment' as peaceful - a rejuvenating calming space that was nurturing and pleasurable. The feeling of care in one specific context, i.e. treatment, was described as one that generalised to the rest of their lives and embraced a range of positive outcomes, including increased self-esteem and self-worth, enhanced self-care practices, and a greater focus on the self and self-care promotion. Comments illustrating these points included:

"(…) I felt no ownership towards my body and I would act how I wanted ignoring my body and the state of it but the treatment made me feel good, I've quit my espressos and the alcohol fags and pot now. These days I am paying attention to my body and I'm more aware now of anything that might do damage to me. It's done me the world of good and I feel great! (…)" (Patient 69)

"(…) the whole process of treatment was very important for me I realised the importance of being kind to myself. I realised I'm important, to slow down and take care of myself (…) the treatment was a real treat (…)" (Patient 111)

"(…) I could do with a bit of pampering really… (…) (Patient 60)

The last two comments, from patient 111 and patient 60, illustrate how some patients experienced TCMA as a reward; an opportunity to recognise their own self-worth and entitlement to be cared for.

Subtheme 3: coping & resilience mechanisms. Many patients reported that they found TCMA treatment useful in facilitating acceptance and adjustment, examples included:

"…it gives me a degree of respite for my problems I can cope with it all now." (Patient 57)

"…I can live with it now and not let it take over my life." (Patient 104)

"…I now come to terms with my problems (…)" (Patient 94)

The evidence from the data indicated that treatment produced changes in the way patients thought about and understood their health conditions, and the ways in which they had managed those conditions. As detailed above in relation to the 'holistic environment' theme, many patients expressed appreciation for having received an explanation of their health conditions, which led them to a different understanding of their problems, which in turn increased their self‑efficacy. Individuals gained reassurance, renewed hope and the necessary coping skills to manage their health problems, which influenced how they felt about those problems and their treatment, illustrative comments included:

"(…) I was able to make some helpful connections and so improve my general health and wellbeing (…)" (Patient 3).

"(…) I've also been helped on an emotional level, I feel I can cope with the pain and now feeling a lot better in myself I can accept my illness and live a positive life in spite of it (…)." (Patient 82)

Interestingly, evidence emerged from patient commentaries, suggesting that, as well as being an effective treatment for long standing health complaints, TCMA produced beneficial, and completely unexpected, outcomes related to other complaints that were secondary to those long-standing disorders, illustrative examples included:

"(…) my ailments are connected in some way as I notice other things, insomnia, sinus problems, heartburn, nausea have all cleared up too which is wonderful as they were causing me problems as well as my pain so I feel the whole of me has been treated." (Patient 40)

Some patients reported that the treatment resulted in them coping better with surgical recovery, chemotherapy or radiation and many described general improvements to both their health and their immunity, illustrations included:

"(…) made my knee heal quicker it helped a lot with both the pain and the swelling after my operation (…)." (Patient 47)

"When I have acupuncture my health is seriously improved I couldn't tell the last time I had a cold the treatment as it keeps my immune system tuned." (Patient 34)

Treatment also increased resilience and the ability of patients to cope with life generally, illustrative examples included:

"(…) more able to withstand the onslaught of modern life (…)" (Patient 18).

"(…) enable me to manage my normal activities, and increase my hours at work (…)" (Patient 108)

Patient commentaries included descriptions of the influence that TCMA had on their mental and emotional balance; patients explained that treatment empowered them to manage emotional states and stress more effectively, illustrative comments included:

"(…) able to respond calmly rather than react to stressful things (…)" (Patient 59)

"(…) it offsets the negative stress (…)" (Patient 26)

It appeared from the data that TCMA influenced arousal levels allowing patients to confront and analyse their personal problems with greater emotional equilibrium. The

positive effects most often cited were: that the treatment grounded relationships; that it increased tolerance levels in general; and, that it promoted greater feelings of calm in many challenging situations. TCMA treatment was found to be effective in tackling a range of mental health-related disorders, including: stress, anxiety, panic attacks and mood disorders. It was also found to be beneficial for patients who were experiencing less specific and well-defined problems of living, including: coping with problems of survival, poor communication, inadequate relating skills, workplace issues, and a range of day-to-day stresses including anxieties related to undergoing medical treatment. Comments illustrating these points included:

> *"(…) the wife was telling me that I was cross, because I was in pain all the time. I couldn't sleep (…) I don't react so quickly or so strongly to things I'm less grumpy and intense (…) It's made me into a better person (…)" (Patient 92)*

> *"(…) I couldn't cope before with the anxiety that certain situations would produce – I thought I was going insane (…) I feel my anger is directed now, not dispersed and I seem to be able to deal with difficult situations without wanting to withdraw or become defensive or aggressive (…) I can get appropriately angry, deal with it, and get it out of my system (…)" (Patient 62)*

Theme Four: Wellbeing and Quality of Life

The theme of Wellbeing and Quality of Life was concerned with the impact of TCMA treatment on subjective estimates of levels of personal happiness, psychological health and comfort, and general welfare. The key factors that influenced these subjective estimates were: individual health status; personal feelings of belonging and connection to others; perceptions of the extent to which one could enjoy the possibilities of his or her life; and the likelihood of realising personal goals, hopes and aspirations. Many patient comments related explicitly to one or more of these factors, examples included:

> *"(…) it's the nicest and best thing I've ever done for my wellbeing I'm so much happier and take more satisfaction in life (…)" (Patient 63)*

> *"(…) its made my life bearable (…)" (Patient 97)*

> *"(…) I am now happy with life (…)" (Patient 84)*

This theme consisted of two subthemes: 'practical tangible benefits for an enhanced QoL' and 'harmony'. The latter was concerned with patient experiences and

expressions of increased overall satisfaction with life and personal wellbeing, while 'practical tangible benefits for enhanced QoL' was concerned with specific benefits of treatment such as: pain relief; improved coping skills and functioning; more supportive social relationships; and enhanced 'well-being' and quality of life.

Subtheme 1: practical tangible benefits for an enhanced QoL. Some patients reported that TCMA improved their sleep, with references made to both patterns of sleep and quality of sleep, for example, one patient stated that, "the difference in the quality of sleep has made life now completely manageable." (Patient 21). Some commented that Needling treatments, specifically, induced feelings of general relaxation and improved wellbeing, illustrations of this included:

> *"(…) I felt more alive, really energized and good within myself (…) treatment really changed me, brought me to life (…) I can live normally with more energy than I've ever had (…) I used to feel like an empty shell, dead and unreal (…) After my treatments my body feels stronger and well (…) I sleep better and I wake up refreshed (...)." (Patient 31)*

> *"(…) Its like a weight lifted off my shoulders and I feel relaxed and calm about everything and I can refocus again. I come out of the treatment with my mind clear and unblocked (…) treatment is a balancing force I leave here fresh and ok (…) my friends and family notice the difference when I have acupuncture (…) things are much better I am less busy minded and peaceful and can now start to deal with things again. (…)." (Patient 21)*

Patients made many references to feeling more rested as a consequence of increased energy post-treatment; their commentaries suggested that TCMA created perceptions of increased strength and vitality and associated feelings of renewed hope for the future. The improved function realised as a result of treatment enabled patients to achieve personal goals, hopes and aspirations, which in turn created feelings of satisfaction and improved well-being, as illustrated by the following comment:

> *"(…) I have lots of goals to achieve and the thing that would slow me down was the pain. Life is too short to waste! Through acupuncture I have found comfort at last. I have been able to return to normality, now with your skills, time and patience my health has improved and I am not feeling so tired and I am much happier. I can now take limited exercise and social things so I am more active in my social life and can continue with my previous interests (…) It helps me to live a normal life and to be a lot closer to my family and friends (…)." (Patient 56)*

Subtheme 2: harmony. The essence of the harmony subtheme was a happiness and improved well-being that arose from perceived positive changes in personal relationships with the physical and social environment. Relevant comments described a

wide range of experiences including: feelings of peace, calm and stillness; greater mental stability; improved ability to manage stress and negative emotions; improved body awareness; a sense of being more grounded; and, a feeling of being connected with others and the environment. Illustrative examples included:

> *"(…) The treatment here seems to have made a great difference I leave the clinic balanced, positive and happy and afterwards emotionally I can cope better with stressful situations I think it gives you a mental soothing (…) I am more grounded in my body, more aware (…) friends and my daughter have commented that I am standing straighter, or look years younger (…)." (Patient 9)*

> *"(…) acupuncture treatment allows for my Zen time it centers me and slows me right down (…) I feel a physical and mental peace and feel more at peace and at home with myself and my body than I have in a very long time (…) I stop worrying and things aren't going round in my head (…)" (Patient 106)*

Theme Five: Agency

The theme of Agency was concerned with the ability of, and process by which, individuals took action to influence their own health outcomes. Agency concerned the ways in which patients appeared to gain agency and it could be defined as 'power in operation', i.e. it related to how patients used their own internal energy resources to acquire a sense of control over their recovery from poor health. Agency was the antithesis of the passivity and patient vulnerability that many proponents of TCM argue characterises much western medicine; for example, in relation to the challenges of living with chronic ill-health TCMA practitioners would interpret Western Medicine as tending to create a dependent relationship with corresponding feelings of reduced control and restricted decision-making powers. In contrast to this effect, TCMA practitioners might assert that TCMA seeks to empower such patients to take control and make decisions, and patients in this study made comments suggesting that this was the experience they had, which was evident from the following comment:

> *"(…) Acupuncture gives you that little bit of power because you are doing something proactive - without just waiting having things done to you and then just waiting." (Patient 72)"*

This theme consisted of two sub-themes: 'command over health and healthcare' and 'self-agency towards health'. The former was concerned with how patients gained a new sense of control over their lives in terms of the direction of their healthcare and treatment, and self-agency towards health was concerned with how treatment promoted

in patients a motivation and directed action towards improving and maintaining their own health.

Subtheme 1: command over health and healthcare. This sub-theme emerged from patient reports that described how TCMA promoted control over both symptom relief and the care they received from their practitioners. The essence of this sub-theme was captured in the following comment:

> *"(...) I experienced myself as a more effective captain of my vessel (...)" (patient 27)*

The evidence from the narrative texts indicated that TCMA reversed the perceived loss of control and disempowerment that many patients reported experiencing as a result of having relied on conventional Western Medicine.

The TCMA treatment appeared to have created a perceptual shift in patients, and one that was explicitly welcomed by those patients, from perceptions of passivity and helplessness, i.e. created by having had medical decisions made for them, to perceptions of active control over medical interventions, i.e. created by having had various alternative actions towards health explained and choices provided. The following comments illustrated the results of this shift and how patients embraced it:

> *"(...) I feel more in control than I do with my GP (...) It really makes a difference coming out feeling you're doing something positive (...)." (Patient 29)*

> *"(...) I appreciate that I am not just in the system anymore and I have choices, there are many choices towards health and they provide just one (...)." (Patient 99)*

> *"(...) it offers you another way of managing things (...) it does wonderful things for me and I'm thrilled to be actually doing something helpful to control my illness (...)." (Patient 112)*

Agency encompassed the sense of empowerment patients experienced as they took control over their illness, their treatment, their wellbeing and their life more generally; interestingly, as well as descriptions of Agency operating in the TCMA healthcare process, patients also described how it applied to the perceived side-effects of bio-medical treatment. TCMA enabled patient agency in terms of avoiding, limiting or reducing their reliance on prescription drugs, minimising side-effects from drugs and reducing healing times with regards to surgery. illustrative examples included:

> *"(...) I wanted another treatment other than taking drugs, tablets (...) since the acupuncture I still take them but not as much and I have stopped taking painkillers*

so often. I am in control and it's not in control of me! I prefer this to taking several toxic medications and the side-effects of them that lead to even more medical problems (…)." (Patient 105)

In addition, for some patients, TCMA was experienced in terms of it being helpful and successful in relation to them avoiding invasive procedures such as surgery, illustrations included:

"(…) I wanted to have my bladder and fibroid treated with acupuncture so that I don't have surgery." (Patient 72)

"(…) it helps as far as possible to avoid surgery and regain my full healthy self (…)." (Patient 29)

Subtheme 2: self-agency towards health. Patient commentaries described an 'agentic self' that operated to promote a sense of self mastery over improving and maintaining their health; they detailed how being given access to a range of tools in the course of their TCMA treatment resulted in them experiencing feelings of enhanced control and empowerment. These tools included: health education, where patients received new understandings of their health and health problems; education regarding self-healing and self-care practices; and, disease prevention and lifestyle advice. Illustrative comments included:

"(…) made me mentally stronger I feel like I'm tackling my life problems now (…) its helped me feel emotionally a bit more in control (…) (Name) made aware of how I can take care of myself and improve myself to reach a better state of health and also mind and the understanding of things gives me more control (…) it was great to know what I could do myself to reduce the impact of symptoms (...)." (Patient 7)

Narrative texts suggested that having access to knowledge, information and practical advice was a key determinant in patients acquiring the sense of mastery that allowed them to deploy effective coping mechanisms and positively influence their own health problems, and recovery from those problems, as illustrated by the following patient contribution:

"(…) I have control knowing what makes my problem worse or what helps (….) wonderful advice on lifestyle things and I was informed of what I can do to control my attacks and she was also good with giving me advice on how to avoid getting so ill in the future (...)." (Patient 109)

Patient commentaries also indicated that the perceived social support and the sharing of power within the therapeutic relationship promoted an increased sense of

agency in terms of gaining more command over their health and care, which in part arose due to the shift they experienced from perceived helplessness and passivity to control and self-efficacy, this is illustrated by the following comment:

> *"(…) through the needling and the advice here from (Name) on what I can personally do for myself and how best to control my pain without so much medication when I'm away from the acupuncture centre (…) great advice on what I could do myself to control the impact of my symptoms it's very supportive here, a real partnership (…) I've got good at controlling my pains (…)." (Patient 34)*

This theme encompassed how patients' experienced feelings of increasing empowerment as they gained and took control over their illness, their treatment, their wellbeing, and their life more generally.

Summary of Findings from Study 2

Patient narratives that were disclosed on clinic discharge forms provided rich data pertaining to the multi-faceted benefits derived from TCMA and they provided testimony to patient experiences of treatment; when they were asked to comment, in their own words about the outcome of their treatment, patients identified key components of the TCMA intervention. Findings demonstrated connections between both TCMA and its outcomes, and between treatment outcomes and contextual factors, which provided insight into the optimisation of the intervention. Contextual factors ranged from descriptions of the setting where the intervention was implemented, to disclosures of contextual 'barriers' and 'facilitators', to the more dynamic process at play. Thematic analysis resulted in the identification of five themes which together provided insight into, and a way of understanding, the processes that operated in TCMA treatment.

The first theme, 'healing nucleus', described the 'healing context' that facilitated patient reported TCMA outcomes; the patients' experiences of contextual factors that worked together, synergistically, to create a dynamic system in which each component made contributions that built on, and interacted with, contributions from other components which facilitated positive outcomes. As well as the belief that the treatment process as a whole was beneficial, patients referred to individual components of treatment, i.e. techniques, theory, practical action and the therapeutic relationship as a complex whole, that were significant contributory factors in the facilitation of health and healing.

‘Influences on the main complaint’ described the central and determining role that was occupied by patients’ beliefs about the effects and effectiveness (positive and negative) of TCMA and the meaning that patients attached to their treatment and their expectations regarding treatment outcomes. ‘Burgeoning effects’ described the important outcome and role played by beneficial treatment effects that were neither directly related to the presenting complaint(s) nor an intentional primary objective of the treatment. TCMA influenced the facilitation of patients’ personal growth and development in unexpected areas, including changes in outlook, self-perception and self- awareness, and changes in their ability to cope with the demands of daily living. ‘Wellbeing and quality of life’ described the important role that TCMA played on subjective estimates of personal happiness, psychological health and comfort, and general welfare, which were influenced by a range of factors including pain relief, improved functioning following treatment, and patients’ overall satisfaction with life.

Finally, ‘Agency’ described how TCMA promoted in patients a motivation to improve and maintain their own health, and how this aspect of TCMA treatment resulted in reported patient experiences of having an improved sense of control over, and an ability to take direct action to influence, their own health outcomes.

CHAPTER 4

Discussion

This study employed a 'Whole Systems Research' (WSR) methodology to explore the effectiveness of Traditional Chinese Medicine Acupuncture (TCMA) treatments delivered in a clinic setting to patients who presented with a wide range of health conditions and were drawn from a wide range of ethnic and socioeconomic backgrounds, including, most significantly, a majority of people from lower socioeconomic backgrounds.

The WSR design employed in this research involved quantitative research (study 1) and qualitative research (study 2) that examined the effect of a specific style of acupuncture i.e. TCMA. The aim of the research was to provide an understanding of the reported experiences and effects of TCMA treatment in relation to patient health, wellness and quality of life (QoL).

The research outcomes of the present study have contributed to the efficacy body of knowledge on TCMA, including knowledge of possible variations in TCMA outcome in relation to a patient population that had both a diverse profile of socio-demographic characteristics and a wide range of health conditions.

The primary objective of study 1 was to explore TCMA efficacy by investigating changes that took place in patient health outcomes over time, as recorded by patients in Measure Yourself Medical Outcome Profile (MYMOP) i.e. recorded changes in primary symptom, activity and well-being, over six weeks.

Hypothesis: *A significant difference in QoL (individualised health status and wellbeing) will be found between baseline assessment and outcome for acupuncture patients over a 6-week course of TCMA treatment.*

A secondary objective of study 1 was to explore potential variations in TCMA outcome in relation to both, patients' socio-demographic characteristics, i.e. age, gender, ethnicity and socioeconomic statue (SES), and the wide range of health conditions that were reflected in the sample as detailed in Table 2.1 (p. 67).

Study 2 explored TCMA patient perceptions and experiences of treatment efficacy in terms of health, wellness and quality of life. Five themes were identified in the study: (1) healing nucleus, (2) influences on main complaint, (3) burgeoning effects, (4) wellbeing and quality of life, and (5) agency.

The results and findings from each of the two studies are discussed separately, in order to elucidate both, the effectiveness of TCMA as a whole complex intervention that operated in a clinic setting (study 1) and the contributions that were made by component parts of the intervention to the observed beneficial outcomes (study 2).

Study 1: Quantitative Research

Summary of findings. Data was collected from a TCMA community acupuncture clinic based in an area of London serving a diverse community including areas of deprivation; the clinic provided subsidised acupuncture treatments, on a sliding scale, which was in line with its commitment to making TCMA treatments affordable and accessible to the wider public, i.e. a more diverse population than that normally associated with acupuncture use. The research analysed data from a patient population (n = 208) with a demographic profile that had some similarities to, and an important difference from, the demographic profile of CAM and acupuncture use reported in the literature, (Bishop and Lewith, 2010), i.e. the age range of the patients and the fact that they were mainly female is consistent with the literature but, in contrast to the literature that consistently reports most users are white middle class females, in this study most patients were from working class backgrounds (Tables 2.2, p. 68) As can also be seen from Table 2.2, the patient sample was more ethnically diverse compared to the demographic reported for CAM-users generally, (Mathew et al., 2011; Bishop and Lewith, 2010; Keith et al., 2005)

As well as being distinct from most other acupuncture studies, due to the demographic of the patient sample, the present study was different to other acupuncture studies referred to in the literature, in terms of the range of conditions that patients presented, i.e. Witt et al., 2006 argued that back pain is the most common complaint that patients present to acupuncturists but in the present study it was one of only a wide range of other health conditions that patients presented (Table 2.1, p. 67).

The patient population in the present study had completed a series of six consecutive acupuncture treatment sessions over a 6-week period, i.e. at approximately 1-week intervals. Findings from the analysis of the collected data supported the original hypothesis that a significant difference in QoL would emerge between baseline assessment and outcome for TCMA patients over the course of their TCMA treatment

MYMOP profile scores across time, i.e. the effects of TCMA on health status measured over a 6-week period, demonstrate that, over the course of six weeks of TCMA treatments, most patients reported symptom, wellbeing and patient activity improvement, i.e. from baseline assessment & treatment through to five follow-up treatments (treatment 6). The MYMOP provided evidence that TCMA might have been an effective treatment (pp. 92-95)

The present study found that over a six-week period of TCMA treatment patients in the sample reported a significant improvement in terms of presenting condition, activity and well-being, which provided evidence suggesting that TCMA might be an effective treatment for people from a broad range of socioeconomic backgrounds, including people from lower SES groups, with a wide range of mental and physical health conditions.

The subgroup analysis completed in the present study was treated as an exploratory data analysis for the purpose of generating further hypotheses (Altman, 1991); it followed the same procedure as that set out for the primary analysis, but it examined the effects of the TCMA treatment in relation to demographic categories and the various presenting conditions. The findings from the sub-group analysis showed no evidence that the perceived benefits of acupuncture treatment were influenced by a person's gender, age, ethnicity, social class, or presenting condition (pp. 95-99), i.e. all groups benefitted from TCMA treatments.

Comparisons with existing literature. The findings from study 1, that there was evidence suggesting that TCMA might be an effective treatment for people from a broad range of socioeconomic backgrounds and presenting with a wide range of mental and physical health conditions, were broadly consistent with other research findings including from studies that examined the effectiveness of acupuncture delivered to populations with the more common or traditional demographic profile (in which lower SES groups are under-represented), and/or with different patterns of health complaints (e.g. specific health conditions), and/or in settings that were similar and dissimilar to that of the present study.

Witt et al., (2006) found that acupuncture plus routine care produced clinically relevant benefits; Sherman et al., (2009) found that at the end of their acupuncture treatment, and at follow-up, patients who received acupuncture (including simulated acupuncture) experienced greater improvements in terms of both symptoms and functional status compared to those who received usual medical care; and Witt et al.,

(2011) reported that outcome markedly improved in the acupuncture group. These three studies are among the relatively few that have investigated sub-groups of treatment responders and while the findings from the present study are broadly consistent with the findings from these studies, there are some interesting inconsistencies, notably, in the present study TCMA affected all sub-groups.

The Witt et al., (2006) study was a large (n = 3093) randomised pragmatic trial conducted in Germany and it looked at the clinical and economic effectiveness of acupuncture; these researchers identified three 'effect modifiers', i.e. they found that the effects of acupuncture treatments were more pronounced in three categories, one related to presenting condition, i.e. pre-treatment dysfunction, and two demographic categories, i.e. patients under 50 years of age and patients with more than 10 years of schooling. No such effect modifiers were observed in the present study, although the category 'years of schooling' was not explored in the present study.

The Sherman et al., (2009) study compared different styles of acupuncture to usual care for chronic low back pain; they performed a secondary analysis of data from their patient group (n = 638) and concluded that, while there was no evidence for the existence of subgroups of patients that would be more likely to benefit from acupuncture, baseline dysfunction was an effect modifier, i.e. patients who presented with more severe reported levels of low back pain had the most short-term benefit from treatment.

The Witt et al., (2011) study was a very large (n=9990), multi-centre, randomised control study conducted in Germany that looked at the influence of socio-demographic and disease related characteristics on treatment outcome in acupuncture treatment for chronic pain. Witt and colleagues found that acupuncture was more effective in four patient categories: females; those living in multi-person households; those who had experienced failure of other therapies prior to the study; and those who had previous positive experiences with acupuncture. Of these four categories of effect modifier only gender was explored in the present study but, in contrast to the findings of Witt et al., the present study did not find that females were more likely to benefit from TCMA acupuncture treatments.

It is important to recognise that a perennial problem in attempting to distil conclusions from the findings of several studies is that it necessarily involves comparing results and findings across those studies, but such comparisons are not necessarily comparing 'like with like', i.e. different studies typically assess a somewhat

different list of possible characteristics as potential moderators of response to treatment. In reality, the results of the trials outlined above cannot be directly compared to the present study because of differences in the way the data was collected and analysed in each of the studies. For example, whereas the present study collected data from MYMOP forms completed by patients who presented with a wide range of pathologies, the three studies referred to above used other outcome measures and involved patient populations that presented with more specific pathologies, i.e. the studies by Witt et al., (2006) and Sherman et al (2009) collected data from patients who presented with chronic low back pain, and the study by Witt et al., (2011) collected data from patients who presented with chronic pain, i.e. this included, but was not restricted to, chronic low back pain. Furthermore, these three studies all investigated much larger patient samples than did the present study, which might have important implications related to 'power', an issue that is discussed below.

Strengths and limitations. The differences observed in the present study between baseline MYMOP and 6-week follow-up were of a magnitude that, prima facia, suggested that clinically significant improvements were achieved in all domains; however, caution must be exercised in interpreting these findings as being specific to the TCMA treatments because many other factors might have contributed to (or caused) the observed changes, most notably the natural history of the health conditions was a possible explanation for the observed improvements. One limitation of this study was that this factor cannot be assessed due to the lack of a control group; furthermore, this study was retrospective, and research is required from prospective studies before firm conclusions can be drawn about TCMA's process and outcome in this group.

The inconsistency between the findings from the present study and the studies by Witt et al., (2006), Sherman et al., (2009) and Witt et al., (2011), regarding effect moderators, may have been due to differences in statistical power, consistent with the present study being underpowered. According to Foster and Cone (1995) power is a concept related to the likelihood of detecting a significant difference when one exists, i.e. the more power a study has the more likelihood there is that a significant difference will be detected when it exists. According to Houser (2007), sample size is the primary factor that determines if a study has adequate power, in view of which a possible explanation for the present study's failure to detect effect moderators is lack of power related to sample size, i.e. n= 208 for the present study, compared to n = 3093 for Witt et al., (2006); n = 638 for Sherman et al., (2009), and n = 9990 for Witt et al., (2011).

The conclusion is therefore that, in the context of detecting effect moderators, the present study might have failed to replicate the findings of other research because it was underpowered.

Sample considerations and methodological reflections. The sample of patients in the present study enabled detailed exploration and understanding of the central questions posed by the research; however, a limitation arises in relation to inferences that can be made from the findings because the study only examined treatment outcomes of patients that completed six consecutive TCMA treatments, i.e. no data was collected on those patients who did not complete the full six treatments. The latter group might have had various reasons for either stopping or discontinuing treatment, e.g. dissatisfaction with the treatment, an improvement or deterioration of the presenting health condition, or some other factor; and there was the possibility that the actual reason(s) could have had some bearing on the nature of the group of patients that were investigated, e.g. those who completed the six treatments might be regarded as 'committed users' of TCMA who incorporated it into their regular health care as opposed to infrequent users dissatisfied with the treatment outcomes. It is important to distinguish between different groups, such as committed users and non-committed users, because their motivations and perceptual experiences might differ; i.e. those patients who completed all 6 treatments were arguably more likely to have favourable experiences of acupuncture than the patients who discontinued treatment; because the possibility of unknown biases exists, e.g. selection bias, there are limitations on inferences that can be made from the findings of this study to the wider population.

The finding from study 1, i.e. evidence suggesting that TCMA is effective for the full range of pathologies and for groups that have traditionally been under-represented in acupuncture studies has expanded the evidence base for the effectiveness of TCMA; in generating evidence suggesting that neither SES nor ethnicity (i.e. Black, Asian and Mixed Other categories) are effect moderators of TCMA treatment, a tentative conclusion can be drawn that people from middle and working class backgrounds, and people from Black, Asian and Mixed Other categories might in general respond in a very similar way to TCMA treatment and might experience the same beneficial outcomes as the more commonly seen groups that have been investigated in acupuncture studies, i.e. middle class, white females. These conclusions, are however, specific to TCMA treatments and cannot be generalised to all

styles of acupuncture, (Birch & Felt 1999; Birch, 1997; MacPherson & Kaptchuck 1997).

The patients in the present study had health conditions for which acupuncture treatment had previously been shown to be effective including: chronic back pain (Brinkhaus et al., 2006; Thomas et al., 2006; Furlan et al., 2005; Manheimer et al., 2005); neck pain and various other painful conditions (Vas et al., 2006; White et al., 2004); migraine (Linde et al., 2005) and tension headaches (Melchart et al., 2005; Vickers et al., 2004); the study has therefore added to the evidence base that TCMA is a treatment option for people with these conditions; furthermore, it has contributed to the evidence base that TCMA is a treatment option for a wider diversity of people, regarding SES and ethnicity, presenting with these conditions.

There is a paucity of evidence related to how people from lower SES groups respond to acupuncture treatment, a situation that can be explained as the consequence of this group, which is the largest group in society, having been consistently under-represented in the samples that have been investigated in acupuncture studies, which has occurred because people from working class backgrounds have not, in general, used acupuncture. Chamberlain (1997) argued that this under-representation in CAM-use arose because middle class people perceived health as being determined by a subtle balance between physical, emotional, social and spiritual aspects of self, which is consistent with the underlying philosophy of acupuncture and other CAM modalities; this congruence between middle class beliefs and CAM philosophy predisposed middle class people to use CAM. In contrast, working class people have subscribed to a more functional and practical model of health, where the focus has been to simply carry out essential daily activities, e.g. working for a living, an orientation that predisposed them to rely simply on mainstream medicine and only use it when the need arose. Findings from the present study were not consistent with the argument presented by Chamberlain, i.e. the study found people from working class backgrounds who accessed TCMA, perceived their health, wellness and QoL, in the same way as did people from higher SES groups, and more importantly TCMA appeared to work equally well.

The present study has potential implications for the public health, i.e. Long (2013) argued that there is an emerging body of evidence demonstrating both CAM's effectiveness and its potential to enable, support and enhance people's health and well-being. Long did not present an exhaustive list of what he was including under the term CAM but he referred specifically to the style of acupuncture that was evaluated in the

present study (TCMA) in view of which, the findings from the present study make an important contribution to the body of evidence to which Long referred, i.e. this study has produced evidence suggesting that the observed benefits of acupuncture might apply across all socioeconomic groups, and most notably they might apply to people from working class backgrounds. The findings from the present study therefore add another possible dimension to Longs' argument that CAM, and TCMA specifically, has the innovative potential to enhance healthcare systems, promote personal and community well-being and health, and enhance the public health.

Study 1 of this research examined the effectiveness of TCMA as a whole complex intervention that operated in a clinic setting, i.e. the outcomes were the product of all the components working interactively and it is not possible to identify any individual component of the treatment consultations, for example the needling alone or the quality of the therapeutic relationship, as having caused (or contributed to) the observed beneficial outcomes. However, the strength of the WSR approach that was adopted in the present study is that the contribution of those individual components of the treatment consultations were, to some extent, elucidated by the qualitative analysis in study 2.

Future research. In view of the argument that no one school of acupuncture is representative of all other schools (Birch & Felt 1999; Birch, 1997; MacPherson & Kaptchuck 1997) future WSR, investigating the effectiveness, in a clinic setting, of each of the individual styles of acupuncture for the treatment of a wide spectrum of health conditions within populations that are diverse in terms of SES and ethnicity, is warranted.

Conclusion

Although the present study did not have the internal validity of a randomised clinical trial, it has provided real-world evidence, i.e. evidence from a clinic setting, about the perceived effectiveness of TCMA and preliminary evidence regarding its effectiveness for a wide range of health problems. The present study explored the use and efficacy of TCMA and has generated evidence that has illustrated the treatment experiences of patients that received this style of acupuncture; the study has produced evidence suggesting that TCMA might be an effective intervention for a diverse population, in terms of ethnicity and social class, presenting with a wide range of health problems.

Study 1 of this research examined MYMOP scores to determine Traditional Chinese Medicine Acupuncture (TCMA) efficacy in terms of its effect on QoL over a six-week course of treatment. It also examined possible effect moderators for TCMA's treatment efficacy and addressed a gap in the literature, i.e. the study has demonstrated the effectiveness of TCMA treatment for a group of patients that presented with a broad spectrum of mental and physical health conditions, who were diverse in terms of socio-economic and ethnic backgrounds, and who were treated at a subsidised clinic, specialising in TCMA and located in a socially and ethnically diverse area of London.

Study 2: Qualitative Research

Study 2 was qualitative research that endeavoured to understand the experience of TCMA treatment in patients from a diverse population (Table 2.5, p. 83) with a wide range of pathologies (Table 2.4, p. 82); the study provided patient insight into their experiences in relation to treatment effects on health, wellness and QoL.

The patient population for study 2 (N = 117) was drawn from the sample used in Study 1 by applying the inclusion criterion that only those patients who had answered questions on their outcome questionnaire at discharge (Appendix D, p. 213) would be included in study 2; as was the case for study 1 sample, the patient sample in study 2 achieved a better representation of people drawn from a low SES group and from a wide range of ethnic groups, in contrast to the typical reported demographic profile of CAM users, i.e. mostly middle class, mostly white and mostly female (Davis et al., 2011; Bishop and Lewith, 2010; Andrews, 2002; Cherniack, Buono et al., 2001; Senzel, & Pan, 2001; Thomas et al., 2001; Astin et al., 2000).

Study 2 Findings

Patient evaluations of their TCMA treatment were congruent across written commentaries, and findings suggest TCMA outcomes were consistent with the full range of treatment effects outlined in the preliminary model of CAM outcome domains within the whole systems framework as described by Verhoef and colleagues (Verhoef et al., 2006) and discussed below.

How the present study's findings relate to Verhoef et al.'s CAM outcome domains. Although there was a difference in the way themes in the present study, and outcome categories in the work of Verhoef et al. (2006), were conceptualised and

defined, each of the five important CAM outcome domains that were outlined by Verhoef and colleagues, i.e. the physical, the psychological, the social, the spiritual and the holistic, could be identified within the narrative text reported, and the themes that emerged, in the present study.

The Physical domain, which includes aspects of physical wellbeing, was evident from patient reports that referred directly to aspects of their physical wellbeing such as pain reduction, and improvements in physical functioning that allowed them to take part in daily activities and regain 'a sense of normalcy' (patient 77, p. 109). This domain was also evidenced by patient narratives that mentioned TCMA as promoting a 'freedom from limitation' and also described the positive impact that this 'freedom from limitation' had on their lives (patient 56, p. 119; patients 26 & 59, p. 117).

The Psychological domain includes moods and motivations, as well as coping and resilience mechanisms and the fact that these features of psychological well-being were experienced by patients is evidenced by statements referring specifically to improved ability to cope with life generally and increased resilience in managing the demands of daily living (patients 18 & 108, p. 117). In more general terms TCMA was perceived to be effective in ameliorating a range of mental health related disorders, e.g. anxiety, depression and ADHD (patients 25, 44 & 117, p. 108).

The Social domain includes aspects of relationships and social support structures as well as the utilisation of healthcare-related services; these factors emerged in narratives that detailed beneficial outcomes from treatment that, in patient perceptions, created more grounded relationships and improved social interactions, as well as enhanced feelings of calm when managing challenging personal social contacts, and increased tolerance levels for managing and coping with relationships in general (patients 62 & 92, p.118). Patient narratives also included references to beneficial outcomes in the form of social support experienced as a consequence of attending the clinic, for example patients reported having benefitted from authentic relationships in which they experienced high levels of acceptance and empathy from practitioners.

The Spiritual domain includes feelings of relaxation, hope and empowerment and these were all reported outcomes of the TCMA treatment; many patients commented that needling treatment specifically induced feelings of peace, harmony and general relaxation (patient 21, p.119), others experienced improved levels of optimism and feelings of new hope (patient 25, p.113), and others reported feelings of

increasing empowerment in their lives more generally and an enhanced ability to navigate their lives more successfully.

The Holistic outcome domain incorporates the other four categories, and this was evident from patient descriptions that referred to all four outcomes as well as other narratives in which patients described their experiences using the term 'holistic' or other terms that were recognisably equivalent to it (patients 29 & 90, p.103). In this study the holistic outcome domain was an important contextual factor that was prevalent across all the outcome domains that emerged; it encompassed all the emergent categories because all the treatment outcomes arose from TCMA's 'holistic' philosophy and practice towards health and healing, all the TCMA treatment ingredients interacted, in a dynamic synergistic process that determined the overall treatment effect.

The high degree of overlap between the findings of the present study and the CAM outcome domains identified by Verhoef and colleagues is important because it demonstrates how findings from the present study have corroborated the findings reported by Verhoef and colleagues; furthermore, the overlap provides some indicators of how processes involved in TCMA can be meaningfully described and understood.

Comparisons with existing literature. Patients in study 2 reported beneficial outcomes that were closely related to symptoms of their presenting conditions, including: symptom improvement, pain relief, more energy and strength, and positive changes in emotional, cognitive and physical functioning; consistent with research on important domains in TCMA as discussed above (Verhoef et al., 2006), and other research that has cited 'expanded effects', patients also reported beneficial outcomes that were more broadly related to well-being, including: increased energy levels, more spirituality and spiritual harmony, 'better connection', improved psychological awareness, peace and relaxation, better levels of personal happiness and optimism, improved motivation and perceived self-efficacy. It is also noteworthy that patients reported unexpected personal growth and development in different dimensions of their lives.

Even when these benefits were reported as being short term they were reported as significant, e.g. a temporary relief from pain and/or other symptoms allowed patients to take part in daily activities and to regain a sense of normalcy. Patient comments indicted that they had achieved an affinity with TCMA's philosophy; they reported that, as a direct consequence of the therapeutic relationship, they experienced a range of cognitive and behavioural changes including changes in: health perceptions, values,

beliefs, behaviours, self-monitoring activities, health promoting activities, self-care practices, lifestyle, and more proactivity in taking control over personal responsibility for health and well-being.

Studies by Cassidy, (1998b) and Gould and MacPherson, (2001) are relevant to the present study in so far as they adopted a WSR framework in the investigation of the effectiveness of acupuncture treatment; there are however, a number of difficulties in comparing the findings of these two studies with findings from the present study which arise because of the way different themes, or outcome categories, are conceptualised and defined in each study. It is unsurprising to find that different categories across and within the three studies (the present study and the studies by Cassidy (1998b) and Gould and MacPherson (2001)) cannot in general be matched for equivalence, in view of which, findings will not be examined by reference to the categories but by reference to elements that can be compared across the studies, such as common reports of improved ability to cope or enhanced energy levels.

Findings from the Cassidy (1998b) and Gould and MacPherson (2001) studies are congruent with treatment effects outlined in the preliminary model of CAM outcome domains within the whole systems framework (Verhoef et al., 2006), and acupuncture treatment outcomes, regarding expanded effects of care, were similar to the present study including: the physical, emotional, spiritual, and behavioural changes, and outcome categories that describe relief of presenting symptoms, reduction in medication, increased energy and calm and relaxation. Cassidy (1998b) and Gould and MacPherson (2001) reported findings that are similar to those of the present study, e.g. patients valued aspects of the process of care as well as experiencing more symptomatic benefits of treatment, and patient-practitioner relationships promoted positive patient behaviours including: health literacy; avoidance of (or less dependence on) medication; and, general feelings of personal empowerment that translated into patient ability to both care for themselves better and to 'navigate' their lives more successfully. Both the Cassidy, (1998b) study and the Gould and MacPherson (2001) study identified valued benefits relating to holistic care, specifically, attention to the "whole" physical, mental, emotional spiritual, and social bodies. Gould and MacPherson (2001) reported that, over time, both treatment-motivations and the focus of treatment became orientated towards the maintenance of health and wellbeing. This congruence between findings from the present TCMA study and previous WSR acupuncture research suggests that the population of general acupuncture users and the population of TCMA users have

had common outcome experiences which might be directly attributed to the intervention.

Long (2002) argued that there are three types of effects that arise from CAM interventions: (1) effects arising from the interventions philosophy and practice towards health and healing; (2) effects emerging from the patient-practitioner relationship; and, (3) effects brought about by the interventions' techniques; This categorisation of effects provides a useful structure for discussing findings from the present study, which has provided evidence of all three types of effects. Although, it is important to recognise that miscellaneous treatment ingredients probably interacted in a dynamic synergistic process that determined the overall treatment effect (Paterson and Britten, 2004).

Effects arising from the interventions philosophy & practice towards health & healing. This effect is related to the 'healing nucleus' theme (pp 100-106), which runs through the text and is reflected in the majority of patient comments; 'healing nucleus' is intertwined with holism – the concept that patient-centred care incorporates body, mind and spirit within the context of their environment (Pietroni, 1987). Holism has been a key concept in previous research regarding patient perceptions of acupuncture (Paterson and Britten, 2004; Luff and Thomas, 2000; Cassidy 1998), and in the present study patients alluded to TCMA's 'holistic personal approach' and in their written commentaries indicated how they perceived, understood and evaluated the treatment itself and how they incorporated the treatment's influences, values and diagnostic approach. However, this finding is not consistent with findings reported by Cassidy, (1998) and Gould and MacPherson (2001), i.e. these researchers found that, while patients showed familiarity, experience and appreciation of the holistic approach, they did not reveal a familiarity with acupuncture theory or language. In an attempt to explain this finding Cassidy (1998) speculated that American Chinese Medicine practitioners had either failed to teach effectively the Chinese Medicine explanatory model, or they had successfully "translated" a foreign practice into the American idiom.

As well as suggesting that patients valued the TCMA approach to treatment, commentaries from patients in the present study revealed a distinct patient affinity with the treatment itself; TCMA has a fundamentally different understanding of the body than that which is found in mainstream medicine and what emerged in patient commentaries was a clear resonance with this 'different understanding', most significantly in terms of TCMA's holistic philosophy. That CAM users are likely to have holistic health beliefs has long been recognised by researchers, e.g. Astin (1998),

and findings from the present study are entirely consistent with this conclusion; patients associated TCMA's holistic approach with experiences of a more natural approach to healthcare and one that had fewer side effects. Treatments were perceived as natural and therefore safe, and worked in harmony with the body, in contrast to patient perceptions of mainstream medicine as having potentially harmful iatrogenic effects. An interesting finding from the present study was that patients used their experiences and understanding of mainstream medicine as a comparative framework against which they contrasted their experiences of TCMA; a common theme was that, prior to experiencing TCMA treatment, their healthcare needs had not been adequately addressed, a similar finding was reported by Worth and Richardson (1995).

Evidence of attitudes and beliefs consistent with postmodernism also emerged in the present study, most notably: beliefs congruent with holism; dissatisfaction with mainstream medical care; dissatisfaction with side effects of mainstream medical treatment; rejection of authority and medical paternalism; and, a conviction in the importance of taking individual responsibility for health. These findings are consistent with findings that have suggested that CAM user attitudes reflect the predominance of postmodern values and attitudes (Siahpush, 1999; Sharma,1995; Bakx, 1991), and are also consistent with arguments that complementary therapies are likely to be more congruent with patients' philosophical and health beliefs compared to the biomedical model's perspective (Kliger, 2015; Kaptchuck and Eisenberg, 1998; Vincent & Furnham, 1996).

Effects related to factors emerging from the patient-practitioner relationship. In a qualitative study that investigated the treatment effects of five-element acupuncture on patients that presented with MUPS, Rugg et al., (2011) stated that, "acupuncture initially accepted as 'just another referral'- one like many others that had been tried and proved unsuccessful - was valued for the amount of time allotted with a caring practitioner who listened and responded, as well as for the interactive and holistic nature of the sessions". The present study found patient comments were largely consistent with this observation, including positive comments about practitioners' humanistic qualities, e.g. descriptors such as 'compassionate', 'caring', 'empathic', 'friendly' and 'kind' were used. Patients also emphasised the value and importance of the patient-practitioner relationship; they valued being recognised and they defined their relationship using various positive words and phrases including: "feeling heard", "listening", "respect", "acknowledgement", "trust", "being supported", "touched",

"trust", "safety", and "working together,". The importance of the practitioner qualities as identified by patients in the present study was consistent with other research (Entwhistle et al., 2012; Cheshire et al., 2011; Robert et al., 2001) and the key role of the practitioner-patient relationship, as well as the importance that patients have placed on individualised care, has also been reported (Peters, 2000, 2006; Luff and Thomas, 2000; Vincent and Furnham, 1996). Wright and Sayre-Adams (2001) argued that entering into the 'right patient-practitioner relationship' can result in healing, which is a possible explanation of the patient experiences reported in the present study.

The patient-practitioner relationship was identified as beneficial to patients for a number of reasons, including: first, the counselling and psychotherapeutic aspects of the relationship were highly valued, a finding that is consistent with the research of Gould and MacPherson (2001) who argued that providing the space for patients to discuss their concerns openly in the context of a safe and trusting relationship was central to the acupuncture process; second, a desire for greater participation, evident from patient commentaries that suggested patients enjoyed and valued sharing knowledge and power and taking part in discussions that led to a shared perspective, a finding that is consistent with the research of Cartwright and Anderson (1981).

Evidence from the present study suggested that the egalitarian nature of the practitioner-patient relationship encouraged and empowered patients to take greater personal responsibility for their health; patients in the present study evidently appreciated and valued the non-hierarchical and egalitarian nature of the therapeutic relationship which appeared to give them 'agency' and supported their priorities, a finding that is consistent with the research of Evans et al., (2011) and Paterson and Britten (2004). Interestingly, these positive characteristics of the therapeutic relationship have also been shown to facilitate better communication and compliance with mainstream medical advice in studies of mainstream medicine (Britten et al., 2007; Ley, 1988). Patients also described changes in health perceptions that appeared to have produced changes in personal health behaviours, which is consistent with findings reported by Fulder (1998) who argued that the objective of many CAM modalities involves the idea that individuals should be assisted in identifying their own healing potential, as this creates the possibility of individual positive change.

It is fundamental to TCMA that practitioners treat the 'whole' patient, which includes offering patient education to promote self-efficacy, and the present study identified patient comments that suggested that this part of the treatment process was

successful, i.e. patient comments included references to better self-awareness and improved understanding of the importance of self-help activities, and references to taking more personal responsibility for health and well-being. Furthermore, these improvements in patient self-efficacy appeared to have positively influenced patient ability to cope, both physically and emotionally. Researchers have offered possible explanations for the beneficial outcomes associated with patient education and related aspects of the patient-practitioner relationship: Mitchell and Cormack (1998) argued that education operated to reduce patient anxiety and promoted feelings of control which led to better outcomes, and Williams-Piehota et al., (2011) argued that advice from the practitioner, and the supportive nature of the relationship generally, interacted with the 'energy' generated by treatment and empowered patients to better manage their illness (as well as other stressors) more effectively in terms of their day-to-day living.

Patient comments in the present study referred to improved coping ability arising from strategies adopted as a result of patient education, which included advice on health, self-care, lifestyle, and disease prevention. This finding is consistent with qualitative research on CAM use, reported by Cartwright and Torr, (2005), Verhoef et al., (2005), and Cassidy, (1998), that suggested that acupuncture treatment had some potential for enhancing patients' coping resources, which in turn empowered those patients to address the challenges of illness as well as more broader life stressors; by re-interpreting stressful circumstances and/or managing personal difficulties more adaptively, patients experienced improvements in wellbeing. Lazarus and Folkman, (1984), argued that coping behaviour involves primary and secondary appraisal, in which individuals evaluate the threat and then consider the availability of coping resources, an argument that might have some bearing on how patients in this study developed better coping strategies.

Many patients in the present study referred to 'coping' better and taking 'responsibility' which echoed the findings of other researchers who have investigated the effects of various styles of acupuncture, e.g. Cassidy (1998) reported that patients took more responsibility for their health, listened to what their bodies were telling them, and were more capable of being 'out of bed without the need to take pain medication'. O'Leary (1985) argued that self-efficacy was an important part of pain management, which offers a possible explanation for positive outcomes in the present study, i.e. by enhancing self-efficacy TCMA might have helped patients in the present study to cope more effectively with pain and pain-related conditions.

Evidence from patient comments in the present study suggested that causal explanations for their illnesses, as well as 'self-care' talk and advice, were highly valued, which is consistent with research findings reported in a number of studies: Coward, (1989) and Cant & Sharma (1995) found that these factors were a major motivator of CAM use; Johannessen (1996) found that the individual oriented nature of CAM treatment provided explanations and solutions that facilitated a functional adaptation to health condition; and Turnquist, Harvey, and Anderson (1998) and Taylor, Lichtman, and Wood (1984) reported that there was an association between cohesive explanations of cause of an illness and the patients adaptation to that illness. An explanation for the findings in the present study is that discussions allowed an explanation of the explanatory models provided by TCMA which helped to provide patients with a framework in which to understand the causal mechanisms underlying their health problems. This is consistent with research suggesting that such frameworks have facilitated patient understanding of their illness, their illness experience, and their understanding of the positive dimension of health (Evans et al., 2011; Cartwright and Torr, 2005).

Patients in the present study described how they acquired, from their TCMA treatment, greater levels of self-agency towards health, reduced dependence on their practitioner, and feeling a greater sense of power and self-reliance; many reported feeling a sense of having more control over their lives, particularly in terms of their personal healthcare and treatment. These reported experiences of personal empowerment following acupuncture treatment are consistent with research in CAM use generally, (Rugg et al., 2011; Cartwright, 2007; Andrews, 2002; Conway and Hockey, 1998). Mitchell and Cormack (1998), argued that the patient-practitioner therapeutic relationship provides an important framework for change, and it is possible that in the present study practitioner attributes may have encouraged patients to participate actively in their treatment and that such participation led to the cognitive and behavioural changes that impacted on their broader lives.

Effects brought about by the intervention's techniques. The effects in focus were those that were mediated by the techniques used in treatment and the skill set of the practitioner, including: diagnostic procedures; skills in needling at the appropriate meridians; moxa treatments, which is the application of heat using a therapeutic herb; use of heat lamps to warm and relax muscles and energy meridians; cupping i.e. the application of glass cups with a vacuum seal placed on the skin to stimulate blood flow

and move ‘stuck’ Qi; ‘guasha’, which is vigorous rubbing of the skin to increase blood flow and move stuck ‘Qi’; electro-acupuncture, which involves very low frequency electrical current (1 Hz) being applied to the acupuncture needle to increase blood flow, relax muscle tissue and move stuck Qi; and ‘Tuina’ therapeutic massage, which relieves muscle tension, opens energy meridians and stimulates the flow of Qi (MacPherson and Kaptchuck 1997). Long (2002) argued that this category of effects is analogous to the effect of drugs or the use of prostheses in mainstream medicine.

Patient comments in the present study indicated that in general they welcomed the full range of knowledge and skills that their TCMA practitioners utilised for their benefit; i.e. their comments conveyed a high level of respect and appreciation for the practitioner’s skills and techniques and many patients described their practitioners as highly professional and knowledgeable, as illustrated by the following, typical, comment:

> *“I really liked (name) his physical examinations of me are really thorough, he’s very skilled and professional, I appreciated that and he really understood my problem so I really did feel reassured by everything (…) better than my GP the GP doesn’t really let you know what is happening and he’s too clinical (…) (Name) gave me lots of information and recommendations and we revised my diet to help with my digestion he taught me to cut back (…) and exercises and advice on activities and posture and that one can avoid such malfunction by learning such techniques to keep the Qi flowing (…) The needles helped so much and I feel so much better, better than I believed was possible.” (Patient.52)*

Patients in this study reported beneficial outcomes that were closely related to symptoms of their presenting conditions, including: symptom improvement, pain relief, more energy and strength, and positive changes in emotional, cognitive and physical functioning; and, consistent with research on important domains in TCMA (Verhoef et al., 2006), they also reported beneficial outcomes that were more broadly related to well-being, including: increased energy levels, more spirituality and spiritual harmony, ‘better connection’, improved psychological awareness, peace and relaxation, better levels of personal happiness and optimism, improved motivation and perceived self-efficacy. Even when these benefits were reported as being short term they were reported as significant, e.g. a temporary relief from pain and other symptoms allowed patients to take part in daily activities and so regain a sense of normalcy.

In addition to the reduction in primary and secondary symptoms following TCMA treatments, patients in the present study reported that they experienced

unexpected personal growth and development in different dimensions of their lives, a finding that is consistent with previous research that has identified improvements in psychosocial coping, including changes in social and personal identity, and the restoration of physical and psychosocial balance as valued treatment outcomes (Patterson and Britten, 2006; Gould and MacPherson, 2001; Cassidy, 1998).

Patients in the present study also reported specific and general improvements in health and wellbeing following TCMA treatment and many referred to its pervasive effects which were described as including positive life-changing experiences. These findings are consistent with 'expanded effects of care' reported in the literature, i.e. 'whole person' and transformational effects that flowed from acupuncture treatments and went beyond the limited scope of the illness, (Patterson and Britten, 2006; Verhoef et al., 2005; Paterson and Britten, 2003; Gould and MacPherson, 2001; Cassidy, 1998). This treatment outcome was encompassed within the theme 'Burgeoning effects' in the present study. The underlying theory of TCMA conceptualises everything in the universe as a different manifestation of the same life force; nothing is separate, and the entire range of human behaviour, personality and intention falls within the province of energetics, in TCMA terminology, it is all part of 'Qi' - the life force. A tenet of TCMA is that rigidities on the level of the psyche externalise to corresponding rigidities on the level of the soma and treating one necessarily impacts on the other (Kaptchuck, 2014).

Research has suggested that the training, diagnostic methods, needling skills and attitudes of an acupuncture practitioner are an important part of the context of acupuncture treatment and might, at least indirectly, be associated with treatment outcomes (Hughes et al., 2007; Paterson and Britten, 2004); Bishop and Lewith (2008) concurred with this view and argued that a patient who had little confidence in their acupuncturist's technical skills was likely to have low expectations in the efficacy of their treatment, which is likely to result in correspondingly poorer outcomes and vice versa. However, in contrast to these arguments, findings from a number of large trials have indicated that practitioner characteristics are unrelated to treatment outcomes, i.e. characteristics such as treatment experience and acupuncture qualifications did not, in these studies, modify treatment effects (Witt et al., 2006; Witt et al., 2006; Witt et al., 2007; Witt et al., 2010 Witt et al., 2011).

TCMA is a procedural therapy and there is evidence from quantitative evaluations that some of the positive outcomes of treatment might well reflect the

patient-therapeutic relationship as opposed to it being a specific consequence of the TCMA treatment, (Bishop and Lewith, 2008; Kaptchuk et al., 2008). Kaptchuk and colleagues argued that beneficial outcomes from acupuncture treatments might be the consequence of a broad amalgam of non-specific effects (some of which are found in all patient-practitioner relationships), including: the diagnostic methods deployed; practitioner attention; the communication of concern; intense monitoring; how a complaint is labelled; and, changes produced in patient expectations and anxiety levels as well as their relationship to quantitative evaluations of their condition. Some evidence supports this argument, e.g. in a trial investigating acupuncture effectiveness for the treatment of irritable bowel syndrome, Kaptchuk et al., (2008) found that an attentive, warm and confident practitioner improved positive outcomes of sham acupuncture; however, other studies including trials that investigated acupuncture's effectiveness for treating osteoarthritis (White et al., 2012; Suarez-Almazor et al., 2010), and questionnaire based research that required patients to rate practitioner empathy (Bishop et al., 2016; Price et al., 2006) failed to produce conclusive findings regarding non-specific effects.

It has been argued that knowledge and expectations might play a major role in acupuncture treatment outcomes (White et al., 2012; Wasan et al., 2010; Kong et al., 2009; Chae et al., 2008; Lewith, White and Kaptchck, 2006), although these arguments have been dismissed by Colagiuri (2012) and Foster et al., (2010) who argued that there was no evidence to support them. Some researchers have argued that psychosocial factors, such as patient perceptions and beliefs of acupuncture's efficacy, have served as a possible determinant of outcome in acupuncture treatment for pain (Bishop and Lewith, 2008); and, psychological factors such as patient self-efficacy and perception of illness might have mediated outcomes. Bishop and Lewith (2016) argued that, in relation to understanding the contextual effects of care and how they might shape treatment outcomes, findings are inconsistent, the evidence is inconclusive, and understanding is incomplete; in view of which it is not possible to identify what caused the observed patient outcomes in the present study.

In common with all healthcare systems, TCMA takes place in a particular context and treatment outcomes can be enhanced or diminished by that context, important elements of the context have been identified as: patient's characteristics, acupuncturist's characteristics, therapeutic relationship's characteristics, treatment's characteristics, and the setting (Di Blasi et al., 2001; Kleijnen et al., 1994). It has been

argued that a contextual factors framework is well suited to understanding acupuncture as a complex intervention because such a framework does not require a distinction to be made between specific and non-specific effects (Paterson and Dieppe, 2005; Paterson and Britten, 2004; Verhoef et al., 2004), and in fact the lack of separation between non-specific effects and direct treatment effects has been reflected in patient evaluations of therapeutic outcomes, which have both recognised the importance of the diagnostic process and emphasised the intrinsic nature of the interaction between physical, psychological and social outcomes.

The benefits of WSR. A fundamental principle of WSR is that an understanding of the different components of complex systems and their interconnections requires exploratory research that combines qualitative and quantitative methods, which is problematical, due to the epistemological and ontological differences between the two research methods. However, a popular solution to the problems posed by attempting to combine these two opposing forms of enquiry, one positivist and one naturalist, is pragmatism – it does not require any particular method or method mix, and does not exclude any, and it was the method adopted in this research. The quantitative research, the TCMA outcome evaluation, together with the written patient narratives that incorporated contextual findings concerning process and outcome, facilitated the interpretation of each data set. The data sets were analysed separately at first, and the knowledge produced by each one examined, then they were brought together and interpreted from a multidimensional perspective, each data set, informed, questioned and enhanced by the other. The findings from study 2 enriched the findings from study 1 and made the analysis much richer and more grounded in the experience of the patients. By examining the quantitative data in the light of the qualitative findings the importance of the contextual factors in determining the quantitative outcomes in relation to patients' main complaints were highlighted, e.g. how the patient practitioner relationship contributed to well-being. The use of WSR has provided rich and complex data and findings about the patient experience and the changes over time, including patient perceptions of what was important to them within that experience. Combining quantitative and qualitative sources of data provided some evidence of positive impacts on wellbeing for patients in addition to illustrating the complexity in how those effects were experienced and sustained over time.

***Implications for practice*.** The present study highlighted the value of Whole Systems Research (WSR) in TCMA treatment evaluation, i.e. it facilitated the identification of key features, processes and multiple effect dimensions, inherent in this style of acupuncture, that were both valued by patients and impacted positively on their health, wellness and QoL. The evidence suggested that TCMA enhanced health and wellbeing and was an effective treatment for the broad spectrum of illnesses that were presented by a patient sample that was diverse in terms of SES and ethnicity; however, it is important to recognise that the TCMA treatments that were delivered to those patients, involved a whole healthcare system and not just needling alone, i.e. while the majority of studies on the effectiveness of acupuncture have focused on needling as the active (and sometimes the only) component of acupuncture treatment, the non-needling components, that were delivered to the patient group in the present study, were delivered according to the diagnosis received by the patients, were driven from TCMA theory, and were integral to the process of care; if they were considered to be either incidental or non-specific or placebos then the value and benefits of the treatment that was delivered would not be accurately assessed, (MacPherson and Thomas, 2008; Patterson and Dieppe, 2005).

Patient comments in the present study suggested that the TCMA practitioners were particularly good at developing positive therapeutic relationships, a skill which has been identified as playing a central role in whole healthcare systems, (Boon et al., 2007; Verhoef et al., 2005). This finding, that patients valued the positive therapeutic relationship aspect of their care in relation to their health has important implications for the healthcare sector; the changing needs and values in modern society were reflected in patient's comments and TCMA appeared to be of value as an alternative approach to the prevention and management of illness. The failure of mainstream medicine to reflect these societal changes and the wider cultural shifts has resulted in it becoming politically and culturally out of step with a growing section of the population and Long (2013) argued that healthcare providers should aspire to attain the qualities associated with TCMA (and other CAM modalities) in order to enhance patient healthcare outcomes.

The present study has demonstrated that the promotion of health and wellbeing is well embedded within the TCMA treatment context; it is interesting to note how this feature of TCMA was assimilated to high level by patients and, significantly, how it changed their health behaviour; the evidence from this study is that changes in patient

health behaviour enabled those patients to adjust and cope with their illness, regain control over their health and experience positive health outcomes. Patient comments suggested that, as a direct consequence of the therapeutic relationship, they experienced a range of cognitive and behavioural changes including changes in: health perceptions, values, beliefs, behaviours, self-monitoring activities, health promoting activities, self-care practices, lifestyle, and they proactively took control over personal responsibility for their health and well-being.

TCMA's core principles and values are oriented towards supporting and sustaining health and wellbeing, which is highly relevant to the field of public health, and it is in the field of public health where TCMA (and other CAM modalities) might have the potential to make substantial contributions. Research has drawn associations between the public health movement and health promotion paradigms associated with CAM (Long, 2009, 2013; Schuster et al., 2004) and has indicated that the use of CAM may be one possible avenue for changing health behaviours (Williams-Piehota, 2011; Long, 2009; White et al., 2008).

Long (2013) argued that CAM, and acupuncture specifically, have the innovative potential to enhance healthcare systems, promote personal and community well-being and health, and enhance the public health; the findings from this study are relevant to this argument, i.e. this study has produced evidence that the observed benefits of acupuncture might apply across all socioeconomic groups, and most notably the findings suggest that the benefits apply to people from working class backgrounds as much as they do to people from middle class backgrounds, a finding that adds another possible dimension to Long's argument.

Uniqueness of the Present Study

There is a paucity of research on the effectiveness of acupuncture treatments generally, and TCMA specifically, in relation to outcomes for people from lower socioeconomic backgrounds and from cultural backgrounds other than white middle class. This situation has arisen because the demographic of CAM users including acupuncture users, have not included these groups, which in relation to people from working class backgrounds is the largest in society, as a consequence, research findings from most studies cannot be generalised. The present study adopted a WSR methodology to explore TCMA outcomes in a more diverse treatment population than has typically been the focus of research, most notably the present study had a better

representation of low SES groups and a wide range of ethnic groups. Additionally, study 1, focused on identifying moderators of TCMA's effects; characteristics such as ethnicity, gender, and the full range of physical and psychological conditions were investigated as possible moderators of treatment efficacy in order to determine for whom the intervention had been beneficial and for whom it had not been beneficial (or not as beneficial). The present study endeavoured to address to some extent the gap in the research (discussed above) and deepen the extant knowledge base regarding this wider populations' perceptions and experiences of TCMA treatment.

Research contributions & significance. RCT studies of acupuncture's efficacy have produced inconclusive and contradictory findings due to an array of methodological challenges. This study adds empirical evidence to the philosophical and theoretical arguments for taking holism into account when evaluating TCMA and other CAM therapies.

Findings from the present study show that TCMA delivered perceived global and multidimensional beneficial changes in health, wellbeing and quality of life; furthermore, the perceived positive treatment outcomes, which were unrelated to illness severity at the time of initial treatment, were consistent across socio-demographic subgroups and a wide spectrum of challenging cases of both physical and mental pathology. These findings are important, because they advance the understanding of TCMA treatment efficacy and the workings of this particular style of acupuncture in terms of health, wellness and QoL. This study has shown that a range of outcomes were important to people and, significantly, it elucidated the dimensions of patient experiences; the findings have promoted a broader perspective on healthcare, which has advanced the understanding of the process by which TCMA produces beneficial outcomes.

The present study is important because (as well as potential contributions made to improved health care and ultimately individuals' health status) the findings are congruent with findings from other WSR acupuncture studies, which suggests that the population of acupuncture users generally, and the population of TCMA acupuncture users specifically, have had common experiences which may have been directly attributed to the intervention.

The combination of qualitative and quantitative research (study 1 and study 2) that did not employ clinical trial/RCT methodology was an important feature of this study because it allowed the examination of patient experiences in a clinic setting; the

study is unique and distinguished from other studies cited earlier, because, in addition to the clinic setting, it focused on one style of acupuncture delivered to patients, who were socially and ethnically diverse and who presented with a wide spectrum of challenging physical, mental and psychological pathologies. This study has made a valuable contribution to the WSR body of evidence in that it has provided valuable information on TCMA and health outcomes in the UK; furthermore, it has demonstrated the value of WSR in the identification of the mechanisms and effects of TCMA from the patient's perspective, i.e. the research was valuable in that it ensured that the evaluation of TCMA was both clinically and value driven.

The range of treatment outcomes that emerged in the present study is evidence that TCMA is a multi-component, complex intervention, and the findings extend the body of knowledge on the whole systems approach, in particular the range of potential patient related outcomes. The findings in relation to the outcome domains that were identified in this research are particularly significant because they are consistent with, and therefore corroborate, findings regarding outcome domains that have been reported by a number of CAM researchers (Verhoef et al., 2006; Verhoef et al., 2005; Paterson & Britten, 2004; Miller et al., 2003; Long, 2002), and the findings are therefore relevant in the context of the development of new outcome measures relevant for acupuncture research. The process evaluation element of the present study was important because it promoted an understanding of how TCMA worked in practice, and therefore made a contribution to an evidence base that can inform policy and practice (Moore et al., 2015).

Finally, there is a recognition in the research community that, for complex interventions, preliminary descriptive and theoretical work is necessary before designing and performing full scale efficacy and effective trials (Campbell, 2000), in relation to which the present study has made a valuable contribution that can inform future research.

Strengths and Limitations of the Research

As observed above the demographic characteristics of the patient sample in this study differed from the recognised demographic of CAM use, i.e. the present study had a better representation of people from lower SES backgrounds and more ethnically diverse backgrounds compared to other studies. Furthermore, in contrast to many acupuncture studies that have focused on a single or discreet group of pathologies the

present study investigated a wide spectrum of physical and psychological pathologies. The study was conducted at a single centre chosen explicitly for the access it had to this patient group, i.e. the study was conceived to investigate the effectiveness of acupuncture in treating a broad spectrum of pathologies presenting in patients more representative of the general population compared to the typical population of CAM users.

The present study revealed aspects of TCMA care and treatment that were valued by patients from a wide spectrum of social and ethnic backgrounds and many of the findings from this study were congruent with other acupuncture research, there is therefore the possibility that TCMA might be applicable to other health care settings; however, a significant limitation of this study is that it is retrospective, and research is required from prospective studies before firm conclusions can be drawn about TCMA's process and outcome in this group.

Sample considerations and methodological reflections. The sample of patients in the present study enabled detailed exploration and understanding of the central questions posed by the research but inferences that can be made from the findings are limited because the study only examined treatment outcomes of patients who completed six consecutive TCMA treatments, i.e. no data was collected on those patients who did not complete the full six treatments. The latter group might have had various reasons for either stopping or discontinuing treatment (e.g. dissatisfaction with the treatment, an improvement or deterioration of the presenting health condition, or some other factor), and there is the possibility that the actual reason(s) could have had some bearing on the nature of the patient sample that was investigated, e.g. those who completed the six treatments could be regarded as 'committed users' of TCMA who incorporated it into their regular health care as opposed to infrequent users dissatisfied with the treatment outcomes. It is important to distinguish between different groups, such as committed users and non-committed users, because their motivations and perceptual experiences might differ; i.e. those patients who completed all 6 treatments were arguably more likely to have had favourable experiences of TCMA than were the patients who discontinued treatment. Because the possibility of unknown bias existed, e.g. selection bias, there are limitations on inferences that can be made from the findings of this study to the wider population.

Study 2 analysed qualitative information from patients who had been invited to provide a narrative of their experiences on 'white space' on their discharge forms, a

method that has particular strengths and weaknesses. O'Cathian &Thomas (2004), argued that the advantage of using white space is that it generates the respondent's own 'story', told in their own words and potentially reveals their reasoning; the disadvantages include the time demands related to analysing the text generated, and the mixed quality of that text. While the 'white space' method potentially allows better access to exactly what patients think is happening during their care, and what features of that care matter most to them, a significant limitation of asking patients to 'tell their story' in writing is that it is biased against people who have poor literacy skills and/or people for whom English is a second language. i.e. it is unlikely that this method generated data from a fully representative sample of TCMA patients at the clinic. It is a limitation of this study that only data from those patients who completed the discharge forms was analysed and little is known about the group of people who did not complete those forms.

Future Research

Findings from the present study have showcased the efficacy of TCMA acupuncture; in view of the argument that no one school of acupuncture is representative of all other schools (Birch & Felt 1999; Birch, 1997; MacPherson & Kaptchuck 1997) future WSR, investigating the effectiveness, in a clinic setting, of each of the individual styles of acupuncture, for the treatment of a wide spectrum of presenting health conditions, within populations that are diverse in terms of SES and ethnicity, is warranted.

Alternative research directions. CAM has been well aligned with health policy emphasis on patient self-management (Department of Health, 2015) and has the potential to contribute to a variety of health-related disciplines. Indeed, researchers have argued that it has a potential role for collaborative alliances with public health (Long, 2013); however, the potential contribution that CAM can make to this area is poorly understood and further research in this direction is warranted.

The findings from the present study have shown the benefits of a different communication pattern, i.e. the TCMA explanatory framework, and has contributed to the research evidence about communications within consulting more widely; findings from the present study, in combination with other research, suggested that there was an association between the therapeutic relationship, successful communication and

outcome in terms of patient satisfaction. Exploration of the TCMA explanatory framework in the light of the above is an unexplored and worthwhile area for research. Many aspects of the value of the positive patient-practitioner therapeutic relationship and its varied influences on beneficial health and wellbeing outcomes have been highlighted in this study; one important finding is that this relationship might have facilitated behaviour change in patients but the study has not revealed how this health behaviour change was facilitated by the TCMA intervention i.e. whether the behavioural change was influenced directly through needling or indirectly through aspects of the therapeutic relationship - this would be an interesting and possibly fruitful area of inquiry.

Concluding Remarks

This research explored the efficacy of TCMA in terms of its impact on health wellness and quality of life and produced evidence suggesting that this style of acupuncture might be an effective intervention for a diverse sociodemographic population, presenting with a wide range of health problems. Some of the contextual findings, for example the development of coping strategies resulting from the provision of information, promotion of lifestyle changes, self-care promotion and the TCMA explanatory framework used to promote new understandings in patients, may have contributed to the outcomes measured on the MYMOP.

This study was not intended to disentangle the individual contributory factors involved in achieving a positive therapeutic outcome; the findings demonstrated the effectiveness of a whole healthcare system on health, wellness and QoL, and patient comments added a richness to the data that provided a personal perspective of their experiences of TCMA.

This research highlighted the value of WSR in identifying the mechanisms and effects of treatment from the patient perspective. Findings from studies 1 and 2 converged which can be seen as an indicator of the study's validity.

In summary, findings from the present study indicate that people measured health as a broader concept than the absence or presence of disease and the study elucidated broader issues in relation to the provision of health care; TCMA appears to have delivered global and multi-dimensional changes and there is a congruence between findings from the present study and other research on different styles of acupuncture, which suggests that the population of acupuncture users in general and the population

TCMA users have experienced similar outcomes, which might be directly attributed to the intervention.

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Research Appendices

Appendix A: Ethics Release Form (page 1 of 3)

Ethics Release Form for Psychology Research Projects

All students planning to undertake research in the Department of Psychology for degree or other purposes are required to complete this Ethics Release Form and to submit it to their supervisor prior to commencing the investigation. Please note the following:

- An understanding of ethical considerations is central to planning and conducting research.
- The published Code of Ethics of the British Psychological Society (1997) Code of Conduct, Ethical Principles and Guidelines. BPS. Leicester and American Psychological Society (1992) Ethical Principles of Psychologists and Code of Conduct. American Psychologist, 47, no 12, 1597-1611 should be referred to when planning your research.
- Approval to carry out research does not exempt you from Ethics Committee approval from institutions within which you may be planning to conduct the research, e.g.: Hospitals, NHS Trusts, HM Prisons Service, etc.

Please answer all of the following questions:

1.	Has a research proposal been completed and submitted to the supervisor?	Yes	☑	No	☐
2.	Will the research involve either or both of the following:				
	2.1 A survey of human subjects/participants	Yes	☐	No	☑
	2.2 An intervention with a cohort of human subjects/ participants, and/or an evaluation of outcome of an intervention?	Yes	☐	No	☑
3.	Is there any risk of physical or psychological harm to participants (in either a control or experimental group)?	Yes	☐	No	☑
4.	Will all participants receive an information sheet describing the aims, procedure and possible risks involved, in easily understood language? (Attach a copy of the participants information sheet)	Yes	☑	No	☐
5.	Will any person's treatment or care be in any way prejudiced if they choose not to participate in the study?	Yes	☐	No	☑

Appendix A (page 2 of 3)

6.	Will all participants be required to sign a consent form, stating that they understand the purpose of the study and possible risks i.e. will informed consent be given?	Yes ☑	No ☐
7.	Can participants freely withdraw from the study at any stage without risk of harm or prejudice?	Yes ☑	No ☐
8.	Will the study involve working with or studying minors (i.e. <16 years)?	Yes ☐	No ☑
	If yes, will signed parental consent be obtained?	Yes NA ☐	No ☐
9.	Are any questions or procedures likely to be considered in any way offensive or indecent?	Yes ☐	No ☑
10.	Will all necessary steps be taken to protect the privacy of participants and the need for anonymity?	Yes ☑	No ☐
	Is there provision for the safe-keeping of video/audio recordings of participants?	Yes ☑	No ☐
11.	If applicable, is there provision for de-briefing participants after the intervention or study?	Yes ☑	No ☐
12.	If any psychometric instruments are to be employed, will their use be controlled and supervised by a qualified psychologist?	Yes NA ☐	No ☐

If you have placed an X in any of the double boxes ☒ , please provide further information below:

Appendix A (page 3 of 3)

Student's Name:

Degree Course:

Title Of Research Project:

Supervisor:

Signature of Student: .....

Signature of Supervisor: .....

Signature of a 2nd Psychology Department member:.....

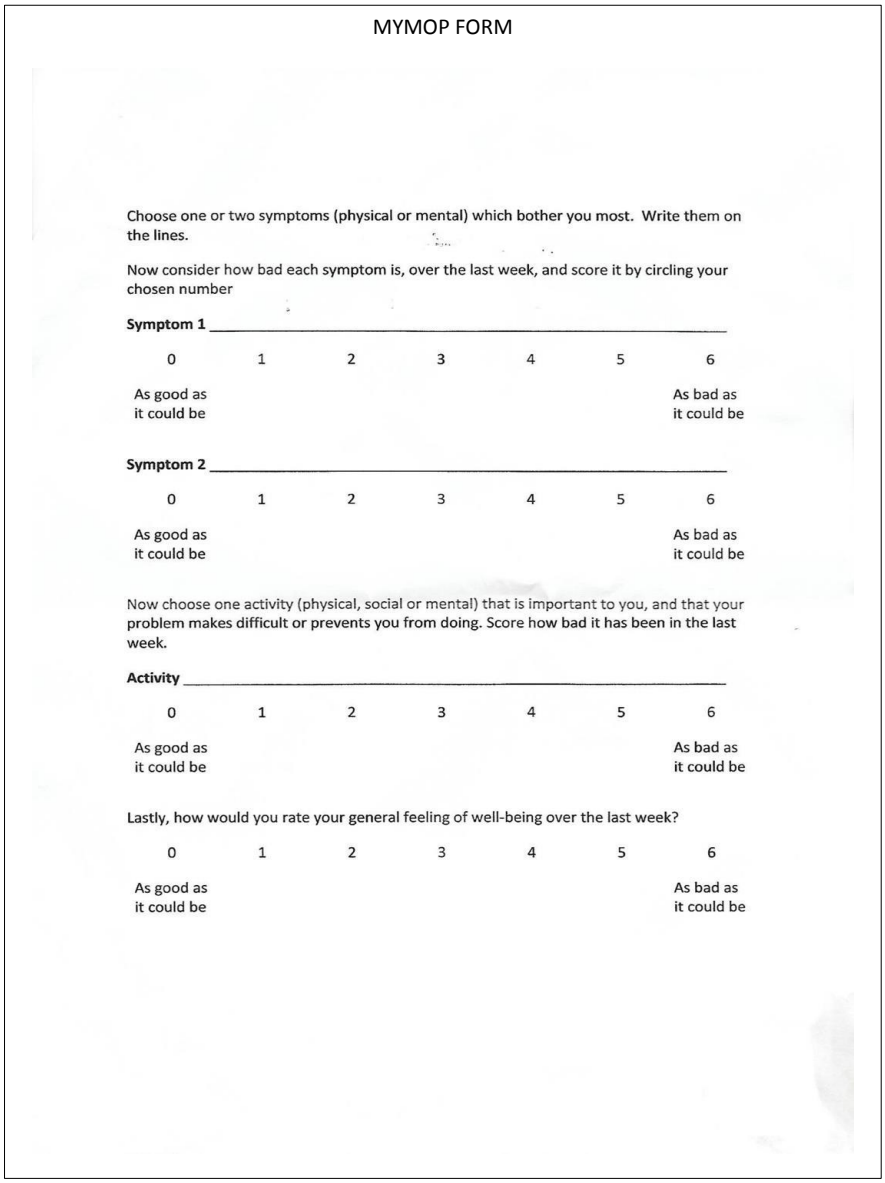
Date: 20/5/06

Any further comments:

Please attach a copy of the participant's information sheet and return this form to:

Liz Caine
Research Development Coordinator
School of Social Sciences
City University
Northampton Square
London
EC1V OHB

Appendix B: MYMOP Form



MYMOP FORM

Choose one or two symptoms (physical or mental) which bother you most. Write them on the lines.

Now consider how bad each symptom is, over the last week, and score it by circling your chosen number

Symptom 1 _____

0	1	2	3	4	5	6
As good as it could be						As bad as it could be

Symptom 2 _____

0	1	2	3	4	5	6
As good as it could be						As bad as it could be

Now choose one activity (physical, social or mental) that is important to you, and that your problem makes difficult or prevents you from doing. Score how bad it has been in the last week.

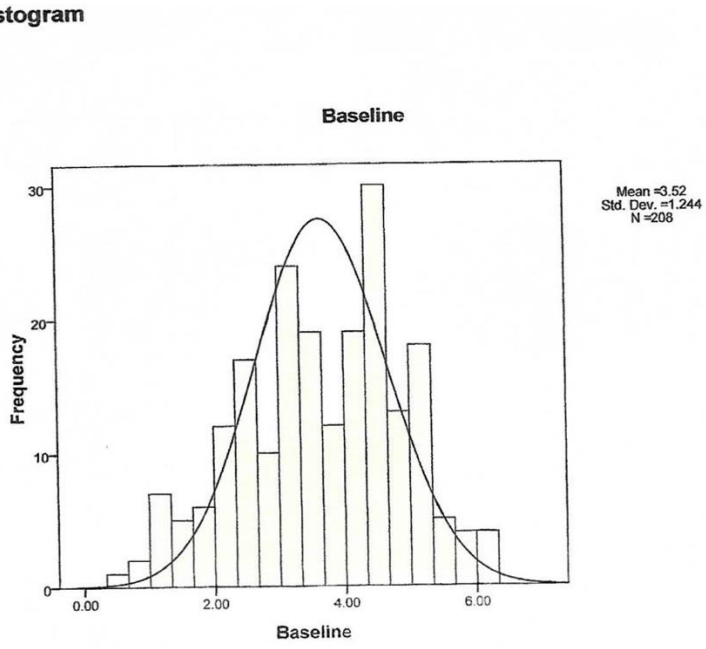
Activity _____

0	1	2	3	4	5	6
As good as it could be						As bad as it could be

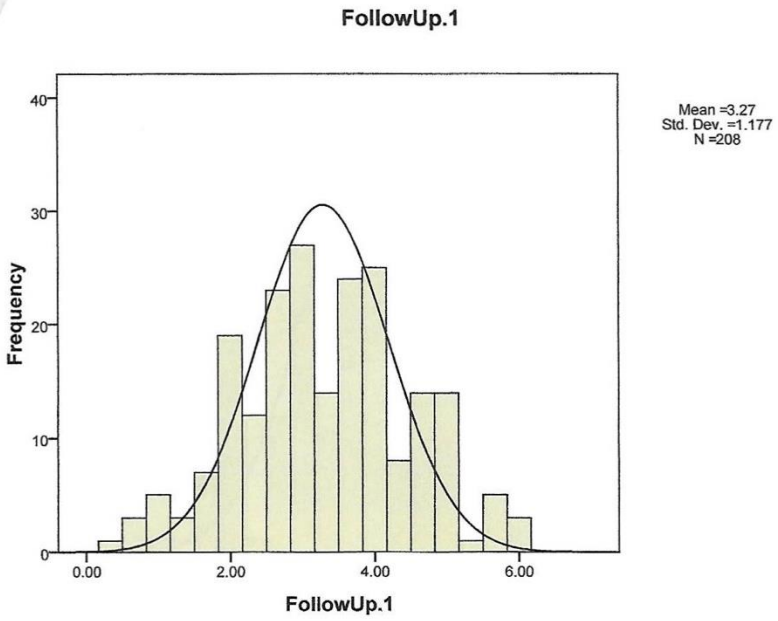
Lastly, how would you rate your general feeling of well-being over the last week?

0	1	2	3	4	5	6
As good as it could be						As bad as it could be

Appendix C: Histograms (page 1 of 7)



Appendix C (page 2 of 7)



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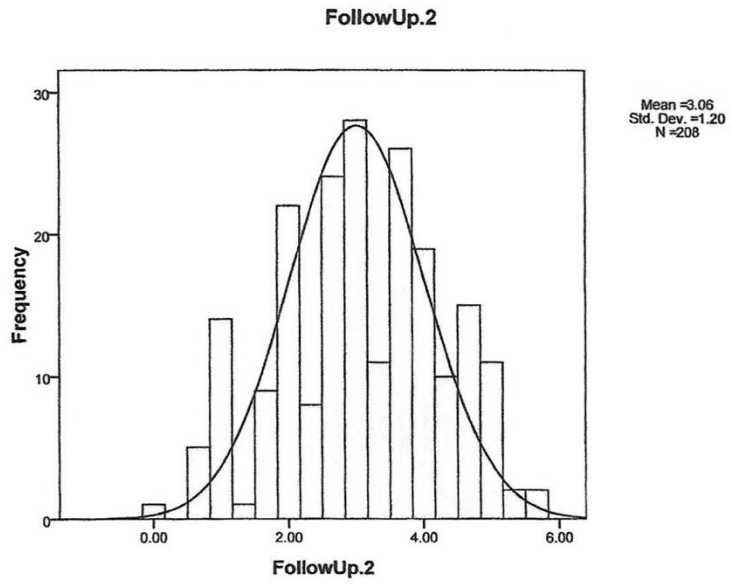
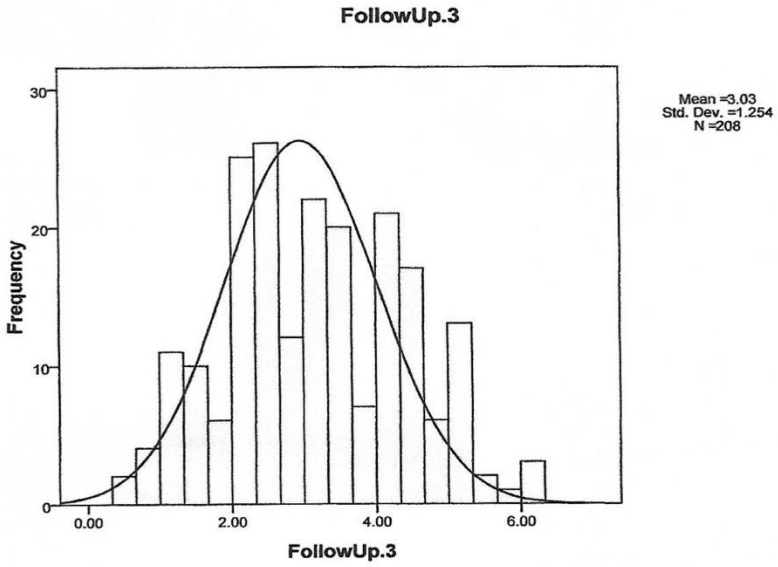
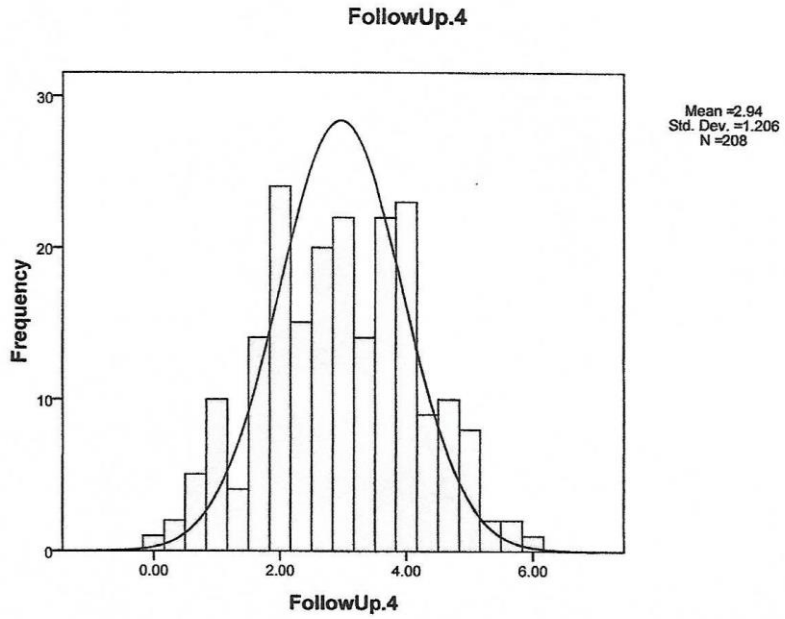
Appendix C (page 3 of 7)



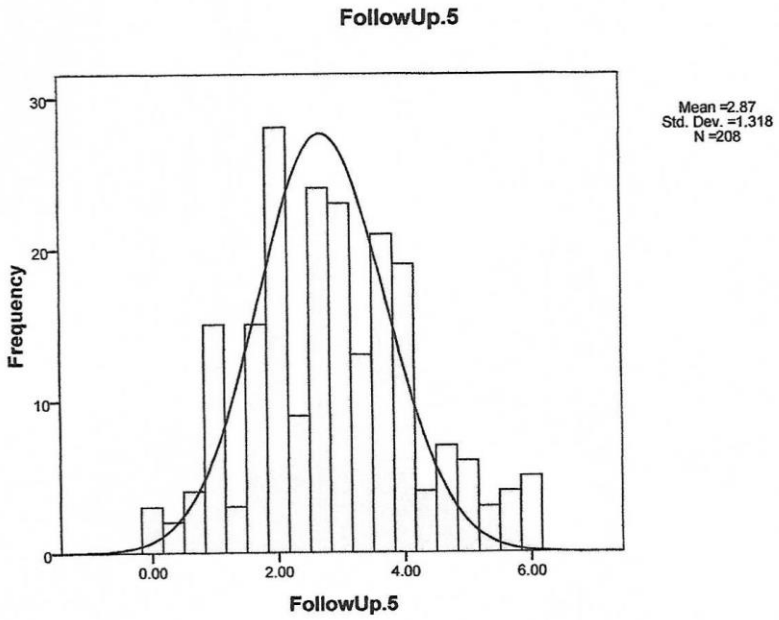
Appendix C (page 4 of 7)



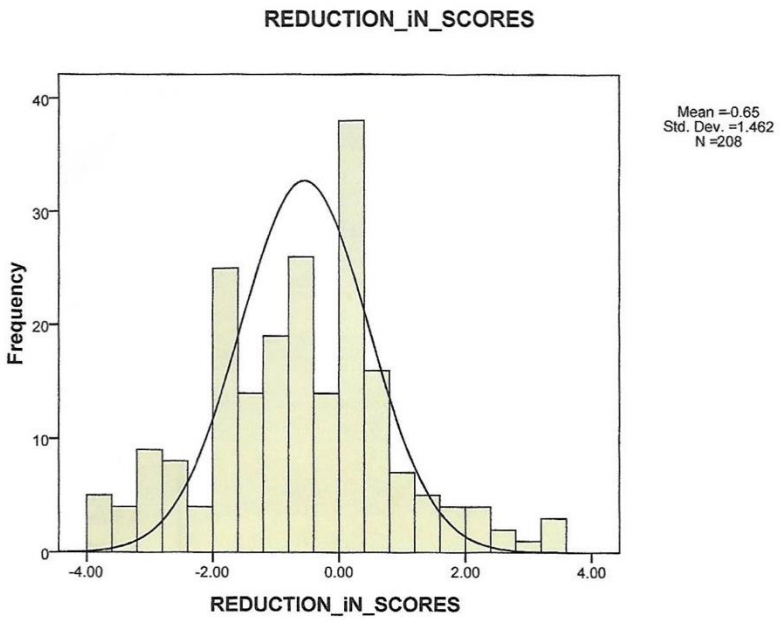
Appendix C (page 5 of 7)



Appendix C (page 6 of 7)



Appendix C (page 7 of 7)



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Appendix D: Patient Discharge Form (page 1 of 2)

[redacted]

[redacted]

Patient Discharge Form

Now that you have completed your treatment we invite you to provide information about your experiences - your views about our service and your views about your own health.

We value information provided on these forms and we use the information to make the service better for future patients.

As well as the questions there is space for you to make any comments you might wish to make (if you need more space please use the back of this form - we read everything you write!)

Thank You

Patient Name: _____

DOB: _____ Age: _____

Attendence from: _____ To: _____ No of sessions: _____

Practitioner(s) seen _____

Main symptoms: 1. _____

2. _____

[redacted]

Appendix D (page 2 of 2)

(Outcome questionnaire at discharge)

What is your opinion on the treatment and care provided at the clinic?

Can you comment on your satisfaction with treatment effects on your illness, health and general wellbeing?

PLEASE ADD ANY COMMENTS YOU WOULD LIKE TO MAKE (USE THE OTHER SIDE OF THIS PAGE IF YOU NEED MORE SPACE)

Appendix E: Example Text from Outcome Questionnaires

I now have few migraines, but some every now and then

I sleep through the night and hardly get up to change, they are reduced to a quarter many as before and are not that intense. I have more energy, not as tired as I used to be

---

The acupuncture it paid attention to me as a whole human being to get the best results out of the treatment. I have been much better with regard to my food intolerance, my bloating and as a result my stomach is working well. Everyday life is much better now due to the relief of hot flashes they are nearly gone. I have maybe had 4 to 5 in a few weeks; those were not as strong as they used to be. I am very pleased with what acupuncture did for me. My life is good now and if I get hot flashes again, I would start acupuncture again

---

Appendix F: SPSS Output File (QoL) (page 1 of 4)

General Linear Model

[DataSet1] F:\data vanessa new variables.sav

Within-Subjects Factors

Measure:MEASURE_1

factor1	Dependent Variable
1	Baseline
2	FollowUp.1
3	FollowUp.2
4	FollowUp.3
5	FollowUp.4
6	FollowUp.5

Descriptive Statistics

	Mean	Std. Deviation	N
Baseline	3.5176	1.24386	208
FollowUp.1	3.2748	1.17711	208
FollowUp.2	3.0601	1.19972	208
FollowUp.3	3.0280	1.25404	208
FollowUp.4	2.9391	1.20588	208
FollowUp.5	2.8654	1.31806	208

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df
factor1	Pillai's Trace	.186	9.296[a]	5.000	203.000
	Wilks' Lambda	.814	9.296[a]	5.000	203.000
	Hotelling's Trace	.229	9.296[a]	5.000	203.000
	Roy's Largest Root	.229	9.296[a]	5.000	203.000

a. Exact statistic

b. Design: Intercept
Within Subjects Design: factor1

Appendix F (page 2 of 4)

Multivariate Tests[b]

Effect		Sig.	Partial Eta Squared
factor1	Pillai's Trace	.000	.186
	Wilks' Lambda	.000	.186
	Hotelling's Trace	.000	.186
	Roy's Largest Root	.000	.186

b. Design: Intercept
Within Subjects Design: factor1

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

	a			
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.
factor1	.549	123.157	14	.000

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
Within Subjects Design: factor1

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

	Epsilon[a]		
Within Subjects Effect	Greenhouse-Geisser	Huynh-Feldt	Lower-bound
factor1	.789	.806	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
Within Subjects Design: factor1

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F
factor1	Sphericity Assumed	60.627	5	12.125	17.157
	Greenhouse-Geisser	60.627	3.945	15.367	17.157
	Huynh-Feldt	60.627	4.032	15.038	17.157
	Lower-bound	60.627	1.000	60.627	17.157
Error(factor1)	Sphericity Assumed	731.451	1035	.707	
	Greenhouse-Geisser	731.451	816.678	.896	
	Huynh-Feldt	731.451	834.529	.876	
	Lower-bound	731.451	207.000	3.534	

Appendix F (page 3 of 4)

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Sig.	Partial Eta Squared
factor1	Sphericity Assumed	.000	.077
	Greenhouse-Geisser	.000	.077
	Huynh-Feldt	.000	.077
	Lower-bound	.000	.077

Tests of Within-Subjects Contrasts

Measure:MEASURE_1

Source	factor1	Type III Sum of Squares	df	Mean Square	F
factor1	Linear	54.954	1	54.954	40.322
	Quadratic	4.503	1	4.503	5.902
	Cubic	.708	1	.708	1.415
	Order 4	.051	1	.051	.101
	Order 5	.411	1	.411	1.008
Error(factor1)	Linear	282.113	207	1.363	
	Quadratic	157.938	207	.763	
	Cubic	103.623	207	.501	
	Order 4	103.296	207	.499	
	Order 5	84.482	207	.408	

Tests of Within-Subjects Contrasts

Measure:MEASURE_1

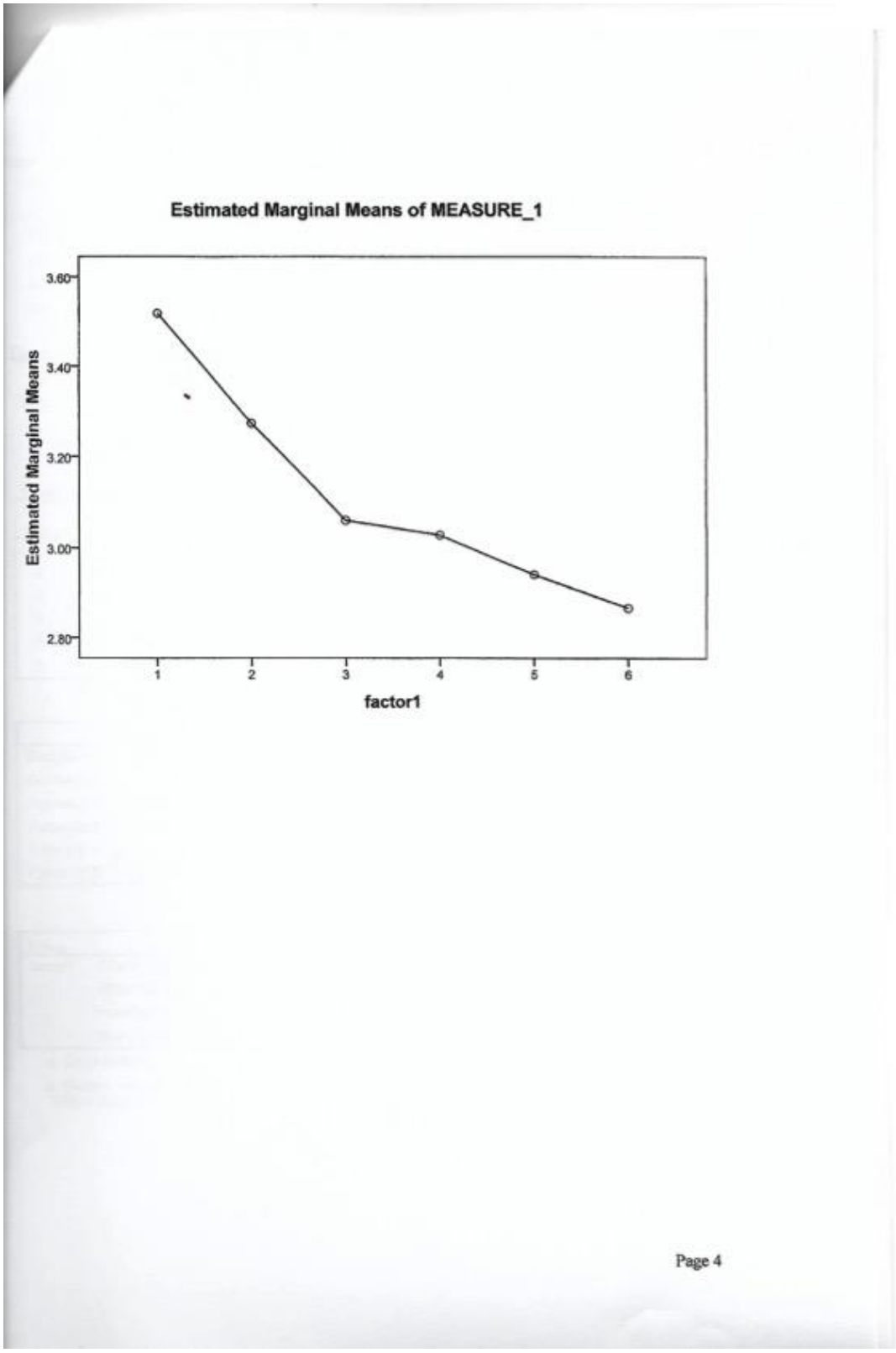
Source	factor1	Sig.	Partial Eta Squared
factor1	Linear	.000	.163
	Quadratic	.016	.028
	Cubic	.236	.007
	Order 4	.750	.000
	Order 5	.317	.005

Tests of Between-Subjects Effects

Measure:MEASURE_1
Transformed Variable:Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	12103.271	1	12103.271	2160.304	.000	.913
Error	1159.734	207	5.603			

Appendix F (page 4 of 4)



Appendix G: SPSS Output File (Symptom) (page 1 of 4)

General Linear Model

[DataSet1] C:\Users\Vanessa\Documents\categoriesreduced2.sav

Within-Subjects Factors

Measure:MEASURE_1

factor1	Dependent Variable
1	P1SCORE.1
2	P1SCORE.2
3	P1SCORE.3
4	P1SCORE.4
5	P1SCORE.5
6	P1SCORE.6

Descriptive Statistics

	Mean	Std. Deviation	N
P1SCORE.1	3.79	1.537	208
P1SCORE.2	3.46	1.544	208
P1SCORE.3	3.17	1.547	208
P1SCORE.4	3.12	1.615	208
P1SCORE.5	3.08	1.528	208
P1SCORE.6	2.97	1.606	208

Appendix G (page 2 of 4)

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df
factor1	Pillai's Trace	.192	9.678[a]	5.000	203.000
	Wilks' Lambda	.808	9.678[a]	5.000	203.000
	Hotelling's Trace	.238	9.678[a]	5.000	203.000
	Roy's Largest Root	.238	9.678[a]	5.000	203.000

a. Exact statistic

b. Design: Intercept
Within Subjects Design: factor1

Multivariate Tests[b]

Effect		Sig.	Partial Eta Squared
factor1	Pillai's Trace	.000	.192
	Wilks' Lambda	.000	.192
	Hotelling's Trace	.000	.192
	Roy's Largest Root	.000	.192

b. Design: Intercept
Within Subjects Design: factor1

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

	a			
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.
factor1	.585	110.086	14	.000

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
Within Subjects Design: factor1

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

	Epsilon[a]		
Within Subjects Effect	Greenhouse-Geisser	Huynh-Feldt	Lower-bound
factor1	.818	.837	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
Within Subjects Design: factor1

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Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F
factor1	Sphericity Assumed	96.283	5	19.257	14.620
	Greenhouse-Geisser	96.283	4.092	23.529	14.620
	Huynh-Feldt	96.283	4.185	23.007	14.620
	Lower-bound	96.283	1.000	96.283	14.620
Error(factor1)	Sphericity Assumed	1363.217	1035	1.317	
	Greenhouse-Geisser	1363.217	847.079	1.609	
	Huynh-Feldt	1363.217	866.297	1.574	
	Lower-bound	1363.217	207.000	6.586	

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Sig.	Partial Eta Squared
factor1	Sphericity Assumed	.000	.066
	Greenhouse-Geisser	.000	.066
	Huynh-Feldt	.000	.066
	Lower-bound	.000	.066

Tests of Within-Subjects Contrasts

Measure:MEASURE_1

Source	factor1	Type III Sum of Squares	df	Mean Square	F
factor1	Linear	82.652	1	82.652	36.500
	Quadratic	10.930	1	10.930	7.148
	Cubic	1.764	1	1.764	1.874
	Order 4	.639	1	.639	.607
	Order 5	.298	1	.298	.373
Error(factor1)	Linear	468.734	207	2.264	
	Quadratic	316.534	207	1.529	
	Cubic	194.830	207	.941	
	Order 4	217.897	207	1.053	
	Order 5	165.222	207	.798	

Tests of Within-Subjects Contrasts

Measure:MEASURE_1

Source	factor1	Sig.	Partial Eta Squared
factor1	Linear	.000	.150
	Quadratic	.008	.033
	Cubic	.172	.009
	Order 4	.437	.003
	Order 5	.542	.002

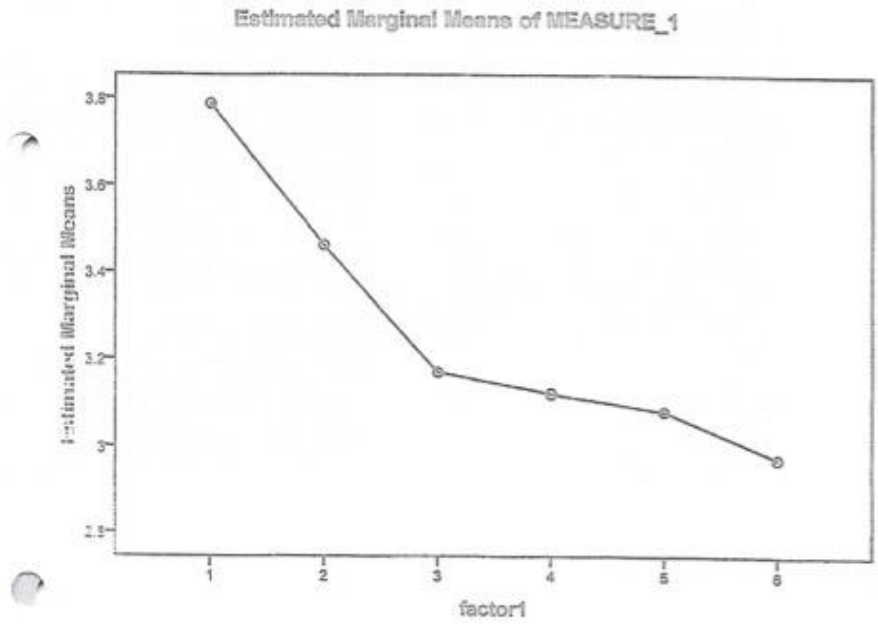
Appendix G (page 4 of 4)

Tests of Between-Subjects Effects

Measure:MEASURE_1
Transformed Variable:Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	13305.789	1	13305.789	1647.693	.000	.888
Error	1671.711	207	8.076			

Profile Plots



Appendix H: SPSS Output File (Wellbeing) (page 1 of 4)

General Linear Model

[DataSet1] C:\Users\Vanessa\Documents\categoriesreduced2.sav

Within-Subjects Factors

Measure:MEASURE_1

factor1	Dependent Variable
1	WBSCORE.1
2	WBSCORE.2
3	WBSCORE.3
4	WBSCORE.4
5	WBSCORE.5
6	WBSCORE.6

Descriptive Statistics

	Mean	Std. Deviation	N
WBSCORE.1	3.16	1.421	208
WBSCORE.2	3.00	1.298	208
WBSCORE.3	2.85	1.236	208
WBSCORE.4	2.86	1.302	208
WBSCORE.5	2.75	1.328	208
WBSCORE.6	2.68	1.388	208

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.100	4.515[a]	5.000	203.000	.001
	Wilks' Lambda	.900	4.515[a]	5.000	203.000	.001

a. Exact statistic

b. Design: Intercept
Within Subjects Design: factor1

Appendix H (page 2 of 4)

Multivariate Tests[b]

Effect		Partial Eta Squared
factor1	Pillai's Trace	.100
	Wilks' Lambda	.100

b. Design: Intercept
Within Subjects Design: factor1

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Hotelling's Trace	.111	4.515[a]	5.000	203.000	.001
	Roy's Largest Root	.111	4.515[a]	5.000	203.000	.001

a. Exact statistic

b. Design: Intercept
Within Subjects Design: factor1

Multivariate Tests[b]

Effect		Partial Eta Squared
factor1	Hotelling's Trace	.100
	Roy's Largest Root	.100

b. Design: Intercept
Within Subjects Design: factor1

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

Within Subjects Effect	a			
	Mauchly's W	Approx. Chi-Square	df	Sig.
factor1	.649	88.770	14	.000

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
Within Subjects Design: factor1

Appendix H (page 3 of 4)

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

Within Subjects Effect	Epsilon[a]		
	Greenhouse-Geisser	Huynh-Feldt	Lower-bound
factor1	.832	.851	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
Within Subjects Design: factor1

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F
factor1	Sphericity Assumed	31.231	5	6.246	8.117
	Greenhouse-Geisser	31.231	4.161	7.506	8.117
	Huynh-Feldt	31.231	4.257	7.337	8.117
	Lower-bound	31.231	1.000	31.231	8.117
Error(factor1)	Sphericity Assumed	796.436	1035	.770	
	Greenhouse-Geisser	796.436	861.228	.925	
	Huynh-Feldt	796.436	881.098	.904	
	Lower-bound	796.436	207.000	3.848	

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Sig.	Partial Eta Squared
factor1	Sphericity Assumed	.000	.038
	Greenhouse-Geisser	.000	.038
	Huynh-Feldt	.000	.038
	Lower-bound	.005	.038

Tests of Within-Subjects Contrasts

Measure:MEASURE_1

Source	factor1	Type III Sum of Squares	df	Mean Square	F
factor1	Linear	29.197	1	29.197	20.635
	Quadratic	.909	1	.909	1.320
	Cubic	.465	1	.465	.687
	Order 4	6.506E-14	1	6.506E-14	.000
	Order 5	.660	1	.660	1.399
Error(factor1)	Linear	292.889	207	1.415	
	Quadratic	142.544	207	.689	
	Cubic	140.124	207	.677	
	Order 4	123.214	207	.595	
	Order 5	97.665	207	.472	

Appendix H (page 4 of 4)

Tests of Within-Subjects Contrasts

Measure:MEASURE_1

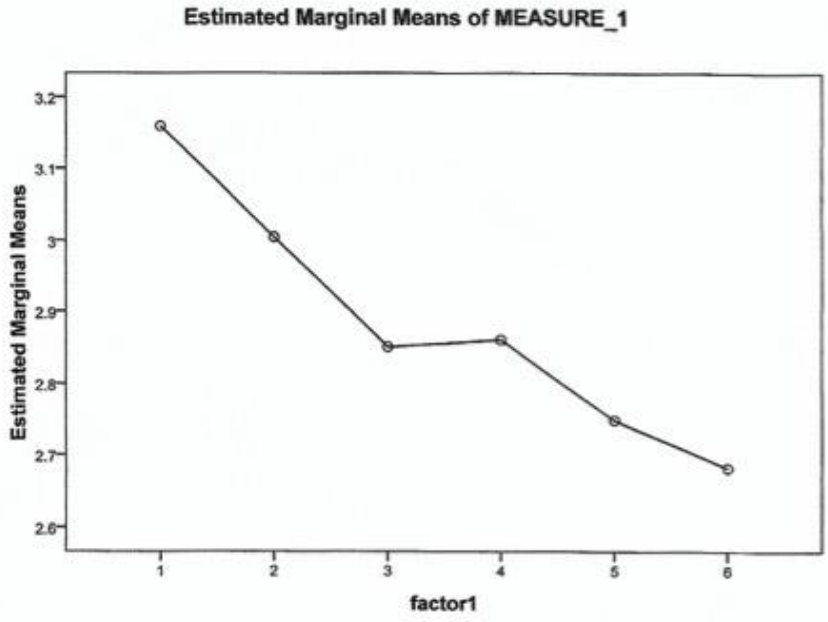
Source	factor1	Sig.	Partial Eta Squared
factor1	Linear	.000	.091
	Quadratic	.252	.006
	Cubic	.408	.003
	Order 4	1.000	.000
	Order 5	.238	.007

Tests of Between-Subjects Effects

Measure:MEASURE_1
Transformed Variable:Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	10384.615	1	10384.615	1533.558	.000	.881
Error	1401.718	207	6.772			

Profile Plots



Appendix I: SPSS Output File (Activity) (page 1 of 3)

Within-Subjects Factors

Measure:MEASURE_1

factor1	Dependent Variable
1	A1SCORE.1
2	A1SCORE.2
3	A1SCORE.3
4	A1SCORE.4
5	A1SCORE.5
6	A1SCORE.6

Descriptive Statistics

	Mean	Std. Deviation	N
A1SCORE.1	3.80	1.702	112
A1SCORE.2	3.47	1.588	112
A1SCORE.3	3.30	1.676	112
A1SCORE.4	3.18	1.532	112
A1SCORE.5	2.93	1.686	112
A1SCORE.6	2.94	1.767	112

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df	Sig.
A	Pillai's Trace	.199	5.320[a]	5.000	107.000	.000
	Wilks' Lambda	.801	5.320[a]	5.000	107.000	.000
	Hotelling's Trace	.249	5.320[a]	5.000	107.000	.000
	Roy's Largest Root	.249	5.320[a]	5.000	107.000	.000

a. Exact statistic

b. Design: Intercept
Within Subjects Design: A

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

	a			
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.
A	.573	60.756	14	.000

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
Within Subjects Design: A

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Appendix I (page 2 of 3)

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

Within Subjects Effect	Epsilon[a]		
	Greenhouse-Geisser	Huynh-Feldt	Lower-bound
A	.801	.835	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
Within Subjects Design: A

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
A	Sphericity Assumed	63.012	5	12.602	9.171	.000
	Greenhouse-Geisser	63.012	4.007	15.727	9.171	.000
	Huynh-Feldt	63.012	4.175	15.091	9.171	.000
	Lower-bound	63.012	1.000	63.012	9.171	.003
Error(A)	Sphericity Assumed	762.655	555	1.374		
	Greenhouse-Geisser	762.655	444.744	1.715		
	Huynh-Feldt	762.655	463.480	1.645		
	Lower-bound	762.655	111.000	6.871		

Tests of Within-Subjects Contrasts

Measure:MEASURE_1

Source	A	Type III Sum of Squares	df	Mean Square	F	Sig.
A	Linear	59.327	1	59.327	25.062	.000
	Quadratic	2.521	1	2.521	1.452	.231
	Cubic	.000	1	.000	.000	.989
	Order 4	1.000	1	1.000	1.063	.305
	Order 5	.164	1	.164	.189	.664
Error(A)	Linear	262.759	111	2.367		
	Quadratic	192.717	111	1.736		
	Cubic	106.755	111	.962		
	Order 4	104.429	111	.941		
	Order 5	95.995	111	.865		

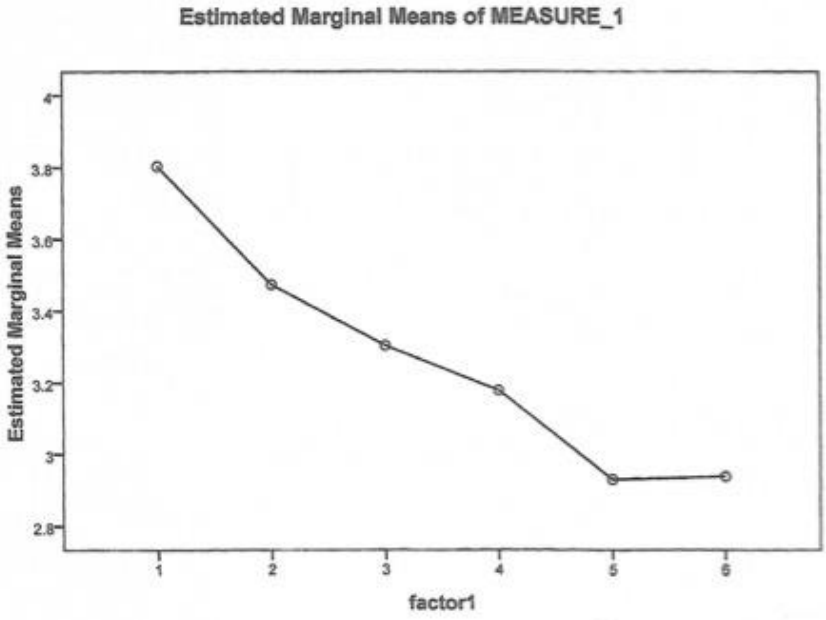
Appendix I (page 3 of 3)

Tests of Between-Subjects Effects

Measure:MEASURE_1
Transformed Variable:Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	7189.292	1	7189.292	743.691	.000	.870
Error	1073.042	111	9.667			

Profile Plots



Appendix J: Patient Text Identifying Positive Impact

Table 3.11: Patients identifying their experiences of TCMA's positive impact on a range of conditions

"(…) problems neck and shoulder blade pain and stiffness and also a stiff painful back. The pain is no longer acute its really eased off in the neck and its now only a dull ache and the shoulder and back are completely pain free and not as stiff as before (…) (Patient 103

"Coming here has really helped me I had an injury climbing. The pain and stiffness in my shoulder is so much better (…) I'm good to go again (…)" (Patient 22)

"It's absolutely fantastic! The last 15-20 years I've suffered ulcerated colitis it's been progressively worse I usually I have diarrhea 9 or 10 times daily. I haven't had any bouts since week 2 of my acupuncture treatment (…) (Patient 45 Lines)

" Its good for my sarcoidosis so far "I have been suffering long term illness since 1990 and I have found comfort at last my aches and pains are nearly gone and I'm feeling nearly as fit as a young child. Thank you" (Patient 53)

"(…) This resource has improved my fibromyalgia noticeably its been the only thing that has worked with my illness (…)" (Patient 104)

"(…) It has made a major difference and I can now go out in public. I am very thankful it has helped with my digestive problems that I have had for years. It also reduced what was very painful rheumatoid arthritis and other ailments (...) The acupuncture has given me a degree of respite for my problems (…) before both my knees were swollen and painful and now I am feeling a lot better" (Patient 93)

" My chronic migraines have reduced in frequency and intensity and Its worked fantastically with PMT and all my womens problems that I've suffered with since my teens (…)" (Patient 32)

Table 3.11: Patients identifying their experiences of TCMA's positive impact on a range of conditions

"(…) problems neck and shoulder blade pain and stiffness and also a stiff painful back. The pain is no longer acute its really eased off in the neck and its now only a dull ache and the shoulder and back are completely pain free and not as stiff as before (…) (Patient 103

"Coming here has really helped me I had an injury climbing. The pain and stiffness in my shoulder is so much better (…) I'm good to go again (…)" (Patient 22)

"It's absolutely fantastic! The last 15-20 years I've suffered ulcerated colitis it's been progressively worse I usually I have diarrhea 9 or 10 times daily. I haven't had any bouts since week 2 of my acupuncture treatment (…) (Patient 45 Lines)

" Its good for my sarcoidosis so far "I have been suffering long term illness since 1990 and I have found comfort at last my aches and pains are nearly gone and I'm feeling nearly as fit as a young child. Thank you" (Patient 53)

"(…) This resource has improved my fibromyalgia noticeably its been the only thing that has worked with my illness (…)" (Patient 104)

"(…) It has made a major difference and I can now go out in public. I am very thankful it has helped with my digestive problems that I have had for years. It also reduced what was very painful rheumatoid arthritis and other ailments (...) The acupuncture has given me a degree of respite for my problems (…) before both my knees were swollen and painful and now I am feeling a lot better" (Patient 93)

" My chronic migraines have reduced in frequency and intensity and Its worked fantastically with PMT and all my womens problems that I've suffered with since my teens (…)" (Patient 32)

Appendix K: Patient Text (Theme 1)

Subtheme 1:

"…I see my acupuncture treatment as a balancing force balancing the yin and the yang I was out of balance (…) acupuncture always does the trick and shifts things a few notches … I feel absolutely wonderful…" (Patient 18)

"…Acupuncture treatment managed to help my many emotional blockages…my energy needed readjusting… acupuncture really swept them right away. I feel amazingly balanced…" (Patient 63)

".. I love that everything is checked, the pulses of the organs and your tongue colour … everything shows what's going on inside… the dampness in my spleen that was causing my bloating went away… and acupuncture increased circulation and everything related to my lungs, kidneys and heart….and you can feel the sensation, an energy and heat and calmness when you are having treatment. She really has got healing hands!" (Patient 112)

"It was so lovely to have the acupuncturist work with you as a whole system I appreciated that (…) he sees me as a whole person (…) it's really a mind body integrated approach (…) acupuncture feels balancing I felt like my whole being and my soul were being looked after as well (….) mental, emotional physical is being touched (…) they didn't leave anything out (…)" (Patient 90)

"After just a few treatments I felt energy building and I'm starting to feel whole again (…) I love the holistic approach that's taken, acupuncture takes everything into account and all aspects of my life are taken into consideration. It's great of (name) to bother to ask me questions (…) I couldn't go to my GP for this. Thank you." (Patient 97)

"(…) I believe acupuncture is vital to mental emotional and physical wellbeing compared to pharmaceutical drugs (…) I got better without the side-effects… a more holistic approach (…) thank you from the bottom of my heart. (Patient 29)

" (…) a more natural approach to my healthcare which my GP cannot provide. They just provide temporary symptomatic relief toxic tablets with side-effects (…) (Patient 108)

"(…) I like to help myself wherever possible and coming for acupuncture treatment really put me on the road to recovery… It was good I got advice on what might make my problem worse or what might help and to help know what the best diet was based on my personal eating practices my social practices etc. and in controlling my pains and avoiding such things in the future (…)" (Patient 45)

"My acupuncture treatment was second to none, (name) was very good really professional and efficient she gave me guidance on things I can do personally to relieve the pain, apart from medication and she gave me exercises which I was told to do them every day (…) She was very reassuring as I was afraid that the arm

would be like that forever (…) she understood what it meant for me (name) is very good at her job (…) the treatment and all of information given was first class she really knew her stuff. She gave me Acupuncture, Chinese Moxa and a rub to take home. It worked really well and my arm is a lot better and I'm in a lot less pain it's not fully straight yet but it's so much better. Thanks for everything." (Patient 48)

"(…) (Name) expert advice is wonderful. I appreciate all she gives me educationally she always has new information to give me and new reading materials (…) (Name) knows what to say to me it's logical and she puts an understandable framework around things (…) she encourages me and I have made lots of lifestyle changes dietary things, exercise, coffee, alcohol (…) coming for acupuncture treatment has strongly influenced the positive change in my health (…) I believe that this approach leads to a lifetime of self-care. Thank you" (Patient 54)

"(…) I was given a satisfactory explanation of my condition, support and understanding (name) showed real interest in my problem (…) so we can work together on the improvement of my health (…)" (Patient 92)

"(…) I like my acupuncturist very much…In acupuncture you are being part of the whole process (…) It's a partnership and I'm not passive in this (…) it makes me feel good that I do my bit too (…)" (Patient 94)

"(…) me and (name) had a full and mutual discussion around things (…) reviewing things together rather than just being told what was going on" (Patient 30)

"(…) self- help techniques and coping strategies such as these are not given to me by my GP (…)" (Patient 103)

"(…) none of the usual medical people no one, my doctor and hospital wanted to help me and then I came here (...) they talk to me and understand my problem and they care. This is nowhere else so I love this treatment (…) my hand is too tired to write more but good things!" (Patient 89)

<u>Subtheme 2: practitioner (and environmental) attributes.</u>

"(…) There was no room for emotional chat in my GP's appointment time (…) I'm very satisfied with the acupuncturist and the treatment, he takes great interest in me as a person and asks me questions and we'd talk (…) I would always feel better after the treatment and really benefited from the time given to help me through emotional as well as physical feelings (…)" (Patient 84)

" (...) I appreciated a full consultation with a practitioner (…) a less hurried approach to my condition was wonderful. (Name) spent endless time with me trying to help with problems whereas the medics attitude is learn to live with it ". (Patient 109)

"I have been very impressed by the service and treatment I have received. (Name) is a very compassionate and caring understanding young woman. I was listened to

(…) very patient (…) a consummate professional these qualities are sadly lacking in general medicine today (…) Thank you for helping me". (Patient 10)

"I wish to say I had treatment by a kind and caring gentleman very friendly person like family". (Patient 51)

"I believe that I was treated with great kindness and understanding by (name), a beautiful person so tender and caring (…) and I feel so much better now so it really worked and I would recommend it to anybody ". (Patient 12)

"I was very impressed and extremely grateful for the kindness and help that I received, and the time that was given to me so that we could find the right treatment for me". (Patient 91)

" (…) always a welcoming atmosphere a wonderful environment and very relaxed. I have found everyone to be very friendly and efficient. (…) her holistic approach and understanding and concern for my many problems is most helpful". (Patient 50)

"(…) also the staff are so lovely. Everyone here is helpful and supportive, they are considerate people and whenever I come here the staff makes me feel welcome (...) I would recommend this to everyone". (Patient 98)

" (…) Great environment too! Service, staff were very friendly and sympathetic. I don't know where I'd be without this place. Everyone needs a service like this where people care about you, from the moment you go in to the moment you walk out the kind treatment continues to be there with you ". (Patient 102)

"The care and the attention I received during my visits for treatment have been top class and I have been treated with great respect. I have felt at ease with (name) and I respect his professionalism (…)" (Patient 107)

"I enjoyed talking to (name) and he made me relaxed, I trusted him very much (…) treatment has helped ". (Patient 11)

" I have benefitted enormously (…) I've felt really connected with (name) she's someone who really cares about 'me' (…) my problems were considered on a personal basis and I was treated as an individual and not just classed as someone else with sleep problems. I am grateful for being treated as someone with individual needs. I appreciate the kindness and understanding and really felt listened to when I was explaining my problems. I could even sit there and cry if I wanted to (…) she really understood me (…) ". (Patient 2)

Appendix L: Patient Text (Theme 2).

"(…) from depression and sleeping problems, to help with the healing of my leg ulcers and more (…) I would highly recommend it (…)" (Patient 113).

Subtheme 1: Improved function: emotional, cognitive and physical domains

"(..) acupuncture is really good for mental clarity (…) my mind is still really, really clear (…)" (Patient 3)

"(…) I am mentally stronger since treatment and I am more able to tackle the problems in my life (…)" (Patient 94)

" (…) with having ADHD I was constantly shifting from one thing to another and could not attend to anything, I was restless and fidgety and couldn't concentrate or focus well (…) I was distracted easily, constantly on the go (…) I am much better now with this (…) I used to have great difficulty organizing and completing tasks now my studies have improved tenfold (…)" (Patient 117)

"Acupuncture improved my life in a psychological way, emotionally (…) it took a few treatments and there were lapses when I'd feel low but the depression has lifted now (…)" (Patient 25)

"This has made a huge impact on my life for the better. I have found the results of my treatment to be profound and amazing, for years I've tried to deal with depression and anxiety with antidepressants and therapy which made me feel worse, suicidal. I would recommend acupuncture treatment to anyone without it I don't think I could function and would have felt bad about myself for years to come maybe I would even be in my grave (…)" (Patient 44)

" (…) I am thankful for (name) and I am very satisfied. It's been a big relief since treatment I owe her everything (…) I was so low and anxious about everything every day and I couldn't relax (...) I didn't know when I was going to have an anxiety attack (…) I didn't go for acupuncture to help me with my depression but I noticed that I was feeling a lot lighter after sessions (…) some of my friends told me that I was easier to be with (…) I've found it to be a lot of good and now my symptoms are less severe and few and far between. (Patient 23)

"(…) I couldn't go out I'd get sweats, problems breathing and feel faint and get strong attacks of butterflies in my chest (…) was a mess and it affected everything (...) I've only had one panic attack in the last month so I am very happy with my

treatment and feel really well and confident and relaxed (…) Thank you for everything I can now get to an exam (…)" (Patient 85)

"I have felt some pain relief for a few days following treatment and a minor general improvement in mobility so it has been helpful for me" (Patient 36)

"(…) which got to be quite immobile I'm impressed with (names) skills (…) I have tried GP's, physio's, osteopaths etc. He pinpointed the exact problem and mobility is back in both shoulders (…) I am so grateful and feel lucky to have found acupuncture (…) before this treatment I was like a bear with a sore head. Thank you so much." (Patient 22)

" (…) 3 weeks after acupuncture my back pain was gone and the awful pain around my hip and all the way down my right leg to my ankle was completely relieved on the third treatment. It's been a great help to me (…) for at least 15 years I've had some sort of back pain and an arthritic hip. (…)" (Patient 4)

Before coming here, I was in constant pain and there are a lot of things I couldn't do. Since coming here, I've not been in constant pain and I've done more than I did before (…) all in all 10/10. (Patient 77)

"(…) I have improved tenfold since my treatment the acupuncture has reduced the inflammation and I've felt much better, less shaky, less pain and I can drive again (…)" (Patient 77)

"(…) definitely benefitted from this acupuncture after treatment one a lot less numbness and tingling in the toes and in my legs (…) It got better and better every treatment a bit better. I have relief of the pressure I work in shop all day standing causing problems for me heavy and aching and veins sometime get lumps and itch with bleeding (…) I feel much happier with it and more comfortable and stand for longer in the shop." (Patient 6)

"(…) suffer with a stitching pain in my stomach sometimes a continuous throbbing on the right side and I found it hard to go to the toilet at times and I could be very constipated or be continuously running to the toilet (…) my stomach looked 9 months pregnant and I had stopped going anywhere social unless unavoidable (…) since acupuncture I'm feeling a lot better and I'm indebted to (name) I can now go to the toilet regularly and normally, and I'm less stressed and have more of a social life my stomach pain has also subsided so I'm happier (…)" (Patient 13)

***Subtheme 2: TCMA treatment as ineffective or achieving limited effects**.*

"My knee pain is easier but still really stiff, for my elbows it hasn't worked (…) maybe my case is too much and too chronic (…) unless its possible to have more regular treatment for a longer time than this (…)". (Patient 79)

"I feel satisfied with the results so far and I am sure that with longer treatment there could be even higher results (…) to be of real value the treatment would need to be longer". (Patient 70)

" It's helped a lot but it started helping at the very end of the course of treatment (…) unfortunately the treatment wasn't long enough (…) more sessions would be more beneficial so I'm just wishing for more sessions". (Patient 8)

" (…) I definitely benefited (…) but the symptoms quickly return in between treatment". (Patient 42)

" (…) It only eases the pain for a couple of days after treatment the pain always returns (…) ". (Patient 51)

"…I am in constant pain and have been for a very long time (…) it helps, but only for about an hour then the pain comes back (…)" (Patient 37)

"I am sorry to say that the treatment has made me worse. I've felt really uncomfortable (…) I'm no better so I'll probably try something else now "(Patient 73)

"I'm feeling no better – just worse!" (Patient 35)

"I would use the service again but maybe use a different acupuncturist". (Patient 17)

Subtheme 3: treatment efficacy as a process.

"I would recommend acupuncture to anyone in pain. The pain disappeared. I did experience a re-lapse and the pain worsened between the 3rd and 4th treatment then it just disappeared. (Name) is wonderful it's really like a miracle." (Patient 101)

"(…) there was a lot of pain, heat and stiffness in my right hip and pain across the top of both feet and in my right ankle from arthritis (…) acupuncture worked for me within one month for my hip that was fine and pain free and my ankle settled but my feet got worse becoming more and more uncomfortable (…) then after a few treatments the pain shifted a bit further down the feet and then it all settled (…) and I've actually attended a dance class again (...). I would like to thank (name)." (Patient 89)

"Fantastic, thank you, incredible (…) Since my car accident and the removal of my spleen, and you working on the spleen, the nerve ends of the spleen and after the second treatment the symptoms gone! (…) the only way I can see that continuing is to get a booster every 2 weeks or every 4 weeks….more please!" (Patient 65)

"I have found acupuncture a great source of relief for many symptoms over the years. Whenever I have it life dramatically improves. I would much prefer this course of treatment rather than taking a multitude of medications. This treatment is very effective for all my past and present ailments and I will always come for booster sessions to keep me going" (Patient 115)

"(…) I do also suffer with a lower back problem I still have that it's intermittent although not nearly as painful as it was (...)" (Patient 80)

“ I have felt improvement with the severe pain that I have had with my period pain which has been with me since a teenager and I’ve got my life back (…) I was wiped out for a full week with it every month and would miss a week of my life (…) the treatment has been fantastic because although I still have some cramps my period has evened out and I haven’t had to take neurophen as much and I used to take 8 a day plus 4 paracetamol (…) so I’m without the side-effects of drowsiness that I felt on that pill combination (…)" (Patient 71)

" A good result. The pain and stiffness in my toes from the neuropathy has been reduced and it is controlled to a tolerable level some cramping remains though much better generally (…) I suffer with arthritis in my shoulder and hips and though the pain is still there it prevents the unrelenting pain and it used to be worse in these winter months, but this treatment is absolutely marvelous." (Patient 43)

“The treatment and centre are superb. Since attending here I’ve found nothing but steady ongoing improvement for many complaints that have been with me for many, many years. My first treatments it made the pain go away part of the time and then every time it staved off the pain more and more for longer amounts of time. I know that I am soon to be pain free.” (Patient 64)

“(…) I’ve had migraine headaches for many years. I have high blood pressure and very high amounts of stress in my life. Since acupuncture bit by bit the pain has become less frequent, less intense and now I will rarely ever get one (…) she is wonderful!”(Patient 32)

Appendix M: Patient Text (Theme 3)

"(…) most of my year-long sufferings have been cured. This makes me more assertive (…)" (Patient 93).

Subtheme 1: Outlook (World View).

" (…) new hope now a light at the end of the tunnel they have shown me (…) life can be looked at from a new angle now and the only way is up (…) it has changed my life (…)" (Patient 25)

" (…) I judge my life differently now and no longer have a stressful outlook towards life (…) carrying on that way would have killed me (…) I am a new human" (Patient 41)

" (…) After treatment the world is the same but you view it differently (…) acupuncture has given me a mentally clarity and allowed me to view the circumstances in my life with more objectivity, It almost gives you the possibility to go outside yourself and look at things from an external point of view (…)" (Patient 16)

Subtheme 2: The changing self.

"(…) my family say I'm back to myself again after 10 years (…) acupuncture has given me back my wellbeing feeling" (Patient 91)

"(…) It's an inspiration to my whole life. When I first came I was shy, nervous, full of anxiety, blood pressure, pain etc etc it has taken me back to a normal way of life" (Patient 12)

"(…) I felt drained life had sucked everything from me treatment has given me back my life and restored me and I am me again" (Patient 102)

"(…) acupuncture helped me get back to myself (…)" (Patient 98).

"(…) I have begun to have a strong interest in my health (…)" (Patient 63) and "(…) for me this has been an essential part of me having a positive attitude and

actions towards my health and wellbeing both physically and mentally (…).” (Patient 96)

“(…) I no longer drink I tried to get drunk a couple of times, but I didn’t like it anymore (…).” (Patient 50)

“ (…) I was someone who drank heavily and had the odd drug or two. The craving for alcohol has completely disappeared. I no longer get depressed and I don’t take anything (…).” (Patient 68)

“(…) now I feel good about myself, I exercise regularly now and work out every morning (…).” (Patient 76)

“(…) I am much more confident and self-assured than I was at the start of treatment, I have gained a courage of my convictions to change certain aspects of my life which I wouldn’t have done before and now I constantly change stuff that isn’t good for me mentally or physically– in my job (…) a complete turnaround since treatment, I handle everything differently everything is better there (…)” (Patient 116)

“(…) on my first visit I had little confidence, but now I am more assertive (…) I haven’t felt this way since 20years old (…)” (Patient 28)

“(…) I always felt that I couldn’t handle anything that I’d fall apart and I was so angry all the time (…) and now that’s all changed thanks to you. I handle stress better and I feel much stronger and can handle anything life throws at me (…)” (Patient 41)

“(…) I was very low but now I feel like I’m on cloud nine! I have never experienced so much movement in such a short space of time, not even in my 10 years of counselling and psychotherapy (…)” (Patient 111)

“(…) Acupuncture seemed to be the vehicle by which this inner knowledge is integrated within me, almost immediately I felt changes happening (…)”. (Patient 27)

“(…) it planted something in me that I slowly started to nurture myself (…)” (Patient 76)

“(…) acupuncture allowed me to re-establish clear contact with my energy, myself (…)” (Patient 106)

“(…) Acupuncture treatment makes me more aware (…) it’s like a positive energy building and I’m increasingly inclined to take the steps that are needed to care of myself and bit by bit I’m doing more to help myself. I believe its set me up for a lifetime of self-care (…)” (Patient 75)

"(…) acupuncture treatment reminds me when I am taking poor care of myself (…)" (Patient 60).

"(…) I'm also beginning to nurture my body back to good health and it's improving the quality of my life both mentally and physically in unison (…)" (Patient 58)

"(…)I felt no ownership towards my body and I would act how I wanted ignoring my body and the state of it but the treatment made me feel good, I've quit my espressos and the alcohol fags and pot now. These days I am paying attention to my body and I'm more aware now of anything that might do damage to me. It's done me the world of good and I feel great! (…)" (Patient 69)

"(…) my self-esteem was rock bottom and I would live like I was in a dustbin with the depression and would have lost my kids to my husband but treatment has turned it all around my symptoms are gone now and I have stopped drinking and my house is lovely (…) slowly I started to help myself and take care of my kids. I owe it all to the needles and the care and attention of (name) she made me feel like I was worth something I'm so grateful for finding her she has been so supportive." (Patient 81)

"(…) the whole process of treatment was very important for me I realised the importance of being kind to myself. I realised I'm important, to slow down and take care of myself (…) the treatment was a real treat (…)" (Patient 111)

"(…) I could do with a bit of pampering really… (…) (Patient 60)

Subtheme 3: coping & resilience mechanisms.

"(…) It gives me a degree of respite for my problems I can cope with it all now (…)" (Patient 57);

"(…) I can live with it now and not let it take over my life (…)" (Patient 104),

"(…) I now come to terms with my problems (…)" (Patient 94).

"(…) I was able to make some helpful connections and so improve my general health and wellbeing (…)" (Patient 3).

"(…) I've also been helped on an emotional level, I feel I can cope with the pain and now feeling a lot better in myself I can accept my illness and live a positive life in spite of it (…)" (Patient 82).

"(…) It's helpful, I'm finding my life easier and more balance to live (…)" (Patient 20)

"(…) my ailments are connected in some way as I notice other things, insomnia, sinus problems, heartburn, nausea have all cleared up too which is wonderful as they were causing me problems as well as my pain so I feel the whole of me has been treated". (Patient 40)

"(…) found that when my symptoms have been reduced in one area they reduce in other areas and I feel better and I'm able to undertake more activities (…) the original reason for undergoing acupuncture was for my eczema and this has

improved mostly I have also noticed a very significant increase in my energy. It improves my overall health (…)" (Patient 8)

"Not only did they deal with the problem that I went there for, but also dealt with and eased my depression following the death of my son". (Patient 19)

"(…) I believe that acupuncture has contributed greatly to a general overall improved health I am feeling healthier and it has definitely stabilized my heath (…)" (Patient 30)

"(…) made my knee heal quicker it helped a lot with both the pain and the swelling after my operation (…)" (Patient 47)

"When I have acupuncture my health is seriously improved I couldn't tell the last time I had a cold the treatment as it keeps my immune system tuned." (Patient 34)

"(…) I get less frequent colds and the symptoms are not as bad and they last a shorter time (…)" (Patient 52)

"(…) more able to withstand the onslaught of modern life (…)" (Patient 18).

"(…) enable me to manage my normal activities, and increase my hours at work (…)" (Patient 108).

"(…) able to respond calmly rather than react to stressful things (...)" (Patient 59)

"(…) it offsets the negative stress (…)" (Patient 26).

"(…) the wife was telling me that I was cross, because I was in pain all the time. I couldn't sleep (…) I don't react so quickly or so strongly to things I'm less grumpy and intense (…) It's made me into a better person (…)" (Patient 92)

"(…) I couldn't cope before with the anxiety that certain situations would produce – I thought I was going insane (…) I feel my anger is directed now, not dispersed and I seem to be able to deal with difficult situations without wanting to withdraw or become defensive or aggressive (…) I can get appropriately angry, deal with it, and get it out of my system (…)" (Patient 62)

"(…) I seem to be able to feel a lot more and act on that feeling (...)" (Patient 15)

"(…) i have been functioning on an emotional and physical level much better since the beginning of treatment (…) I'm coping with my chemo and more generally (…) people are commenting about how I seem calmer about things (…) my nausea and physical energy is much improved and emotionally I can cope better with stress of it all (...)." (Patient 55)

Appendix N: Patient Text (Theme 4)

"(…) it's the nicest and best thing I've ever done for my wellbeing I'm so much happier and take more satisfaction in life. (…)" (Patient 63).

"(…) its made my life bearable (…)" (Patient 97) and "(…) I am now happy with life (…)" (Patient 84).

Subtheme 1: Practical Tangible Benefits for an Enhanced QoL.

"(…) I felt more alive, really energized and good within myself (…) treatment really changed me, brought me to life (…) I can live normally with more energy than I've ever had (…) I used to feel like an empty shell, dead and unreal (…) After my treatments my body feels stronger and well (…) I sleep better and I wake up refreshed (...)". (Patient 31)

" (…) low in energy most of the time people a lot older than myself were better than me (…) I would have to try to get energy to see people and turn my family away so that I could rest. But now even though I did not come especially for this I leave the sessions feeling refreshed and renewed (…) It's doable now, also I have achieved more every day and I can work faster and I can even hike again (…) it gave me a warm relaxed feeling as soon as the needles went in and it also gave me more energy (…) I had enough energy then to pursue the solutions (…) I can do things to help my health (…)." (Patient 29)

"(…) the energy came back (…) I felt the energy building (…) after every treatment I would feel refreshed and energized and had a new lease of life (…) I feel ok again after treatment. I can begin again, re-group and re-focus." (Patient 110)

"(…) Its like a weight lifted off my shoulders and I feel relaxed and calm about everything and I can refocus again. I come out of the treatment with my mind clear and unblocked (…) treatment is a balancing force I leave here fresh and ok (…) my friends and family notice the difference when I have acupuncture (…) things are much better I am less busy minded and peaceful and can now start to deal with things again. (…)" (Patient 21)

"(…) I was desperate, I virtually crawled in here I couldn't walk the 100 yards to the corner shop and now my condition has improved in such a way as to I can now leave the home occasionally. I can keep up with family and friends and keep my independence. It was impossible before acupuncture I couldn't wash and dress myself and now within the six weeks I'm more able (…) acupuncture has made a big difference to the way I can live my life (…)" (Patient 61)

"(…) I have lots of goals to achieve and the thing that would slow me down was the pain. Life is too short to waste! Through acupuncture I have found comfort at last. I have been able to return to normality, now with your skills, time and patience my health has improved and I am not feeling so tired and I am much happier. I can now take limited exercise and social things so I am more active in my social life and can

continue with my previous interests (…) It helps me to live a normal life and to be a lot closer to my family and friends (…)" (Patient 56)

"(…) Acupuncture was given to me on both my knees and my back. Its made me feel so much better (…) I can walk much better and I can sit and not have the pains shooting down my back (…) now I got a bit of relief from the pain I am able to do some jobs I wasn't able to do like household chores (...) I am now happy with life and my motivation for life has improved (…)" (Patient 47)

Subtheme 2: harmony.

"(…) The treatment here seems to have made a great difference I leave the clinic balanced, positive and happy and afterwards emotionally I can cope better with stressful situations I think it gives you a mental soothing (…) I am more grounded in my body, more aware (…) friends and my daughter have commented that I am standing straighter, or look years younger (…)" (Patient 9)

"(…) acupuncture treatment allows for my Zen time it centers me and slows me right down (…) I feel a physical and mental peace and feel more at peace and at home with myself and my body than I have in a very long time (…) I stop worrying and things aren't going round in my head (…)" (Patient 106)

Appendix O: Patient Text (Theme 5)

"(…) Acupuncture gives you that little bit of power because you are doing something proactive- without just waiting having things done to you and then just waiting (Patient 72)"

Subtheme 1: Command over health and healthcare.

"(…) I experienced myself as a more effective captain of my vessel (…)" (Patient 27).

"(…) I feel more in control than I do with my GP (...) It really makes a difference coming out feeling you're doing something positive (…)" (Patient 29);

"(…) I appreciate that I am not just in the system anymore and I have choices, there are manyces towards health and they provide just one (…)" (Patient 99).

"(…) it offers you another way of managing things (…) it does wonderful things for me and I'm thrilled to be actually doing something helpful to control my illness (…)" (Patient 112)

"(…) when I have acupuncture, I am in better control of myself physically and mentally (…) I really notice it if I skip a treatment everything goes screwy (…)" (Patient 90).

"(…) I wanted another treatment other than taking drugs, tablets (…) since the acupuncture I still take them but not as much and I have stopped taking painkillers so often. I am in control and it's not in control of me! I prefer this to taking several toxic medications and the side-effects of them that lead to even more medical problems (…)" (Patient 105)

"(…) I was better but Dr said continue with drugs for a bit. I had side effects so I said no more and took control (…) acupuncture is the best thing I ever did (…)" (Patient 8)

"(…) helps reduce my reliance on prescription drugs. I have been able to get rid of my inhaler and gain control of my asthma (…)" (Patient 100)

"(…) I wanted to have my bladder and fibroid treated with acupuncture so that I don't have surgery" (Patient 72):

"(…) it helps as far as possible to avoid surgery and regain my full healthy self (…)" (Patient 29)

Subtheme 2: self-agency towards health.

"(…) made me mentally stronger I feel like I'm tackling my life problems now (…) its helped me feel emotionally a bit more in control (…) (Name) made aware of how I can take care of myself and improve myself to reach a better state of health and also mind and the understanding of things gives me more control (…) it was great to know what I could do myself to reduce the impact of symptoms (...)" (Patient 7)

"(…) I have control knowing what makes my problem worse or what helps (….) wonderful advice on lifestyle things and I was informed of what I can do to control my attacks and she was also good with giving me advice on how to avoid getting so ill in the future (..)" (Patient 109)

"(…) through the needling and the advice here from (Name) on what I can personally do for myself and how best to control my pain without so much medication when I'm away from the acupuncture centre (…) great advice on what I could do myself to control the impact of my symptoms it's very supportive here, a real partnership (…) I've got good at controlling my pains (…)" (Patient 34)

SECTION C - PROFESSIONAL PRACTICE

Core Unit 1: Generic Professional Case Study

Training Context

I worked as a trainee health psychologist for the Public Health Department (Stop Smoking Service) within the National Health Service (NHS) Primary Care Trust.

Implement and maintain systems for legal, ethical and professional standards in applied psychology. The British Psychological Society (BPS) code of practice code of conduct, 2000; 2006; 2009 dictates that one should abide by four ethical principles: respect; competence; responsibility and integrity. As both a member of the BPS and an employee of the National Health Service (NHS) I have implemented and maintained these practices throughout my training as a health psychologist. Shortly after starting work at the Department of Public Health I was inducted into my role and this fulfilled the legal and ethical requirements for my practice within the NHS. Thus, in addition to BPS guidance I am also bound by the legal, ethical and professional standards of the National Health Service (NHS).

I manage my own caseload of clients and I am required to obtain written client consent to treatment and to maintain client records in line with the confidentiality policy of the Primary Care Trust (PCT). All data from clients is kept in accordance with the Data Protection Act (1998). Information is held for treatment purposes and used to monitor the effectiveness of the service as required by the Department of Health (DH). In order to protect client confidentiality and the security of client information, it has been necessary to both establish and maintain a system for the security and control of the information. Client personal identifiable data is held on a secure database within the department which is password protected. Paperwork held with client data is stored securely in a locked cabinet. Whilst carrying out consultancy and research all sensitive information was deleted and replaced with the participant identification numbers. University Ethical Approval was sought and gained prior to commencing work on the research component of my training.

I train and support the Stop Smoking Service administrators and Health Care Professionals (HCP's) who use the system to record and process sensitive client data of clients who receive smoking cessation interventions. I have ensured that they are aware of their responsibilities regarding consent and confidentiality and are aware of relevant policy, for example, they have been informed or reminded of the NHS confidentiality

code of practice (Department of Health, 2003) and the Caldicott Guidelines (Department of Health, 1997). I have provided guidance to ensure that patient data is kept confidential, for example, clearing the computer screen before sitting with the next client and storing paperwork with sensitive information in a locked drawer or cabinet. Paperwork is to be given to me at my next practice visit and I transport it to the office in a locked case. Once the papers have been processed, they are destroyed. The procedures of transportation and storage of client information are continually reviewed and updated to ensure they adhere to policy. It is my role to ensure that there are secure mechanisms in place for the collection of data. I am involved in changing systems within the Trust so that General Practice systems prompt the carrying out of smoking cessation interventions and I am also helping to roll out the new secure database that will provide a system that is paperless, efficient and secure.

I contribute to the evaluation and monitoring of the service. It is my role to maintain service standards and ensure that the service to clients is provided competently and effectively as well as ethically and in accordance with the Service Level Agreement (SLA) and code of conduct.

I take the lead in developing and delivering the Brief Intervention and Intermediate Level Intervention and training updates throughout the borough. The training is in line with the Health Development Agency (2003) standard that is used by those in the Smoking Cessation field for a coordinated approach to the content and quality of training. I ensure that the HCP's undertake their role in accordance with clinical governance (Scally & Donaldson, 1998). In order to ensure this, I provide post-training supervision, review performance on a quarterly basis and provide the necessary follow-up.

When I embarked on my training I was conscious of the numerous principles, policies and requirements - legal, professional and ethical that needed to be observed and it seemed to some extent like I was having to navigate my way through a minefield. I now feel comfortable with these various stipulations and appreciate how they provide a safe working environment for professionals and their clients. I have developed a considerable awareness of how the required approaches and behaviours relating to ethics, legal demands, confidentiality issues, Data Protection, Professional Standards and informed consent mesh together to form a safety net so that everyone - professionals and clients - are respected and treated in a way that is beneficial and will not cause harm or distress. Furthermore, the awareness that I have developed regarding

these issues has served to enhance my instinctive understanding of the need to constantly monitor the quality of the service I provide.

Contribute to the continuing development of oneself as a professional practitioner psychologist. I routinely maintain my own professional development as a practitioner psychologist and ensure that my supervisory needs are identified and met. I keep abreast of new and relevant evidence-based research in my field and make sure my skills are up to date. I take the lead on training and I have to provide on-going support and advice, and act as an expert resource for HCP's locally. I have attended a three-day specialist smoking cessation training course in addition to which I am a fully certified National Centre for Smoking Cessation and Training (NCSCT) practitioner and have completed all optional speciality modules. I ensure that the HCPs that I mentor are up to date in the area of smoking cessation and tobacco control. In addition, I develop guidelines, protocols, newsletters and reports, and so I have to make sure that I have the necessary breadth of skills and knowledge and that I keep these up to date. This is essential as I have to be credible to clients and professional colleagues if I am to carry out my role effectively.

I incorporate reading into my work schedule in order to broaden my knowledge of research and evidence-based practice and actively locate training opportunities (and subsequently attend the courses) in order to update and consolidate my skills. I regularly read journals including The BPS Health Psychology Update and The British Journal of Health Psychology. I have studied the National and Department of Health (DH) guidance. I attend the monthly Public Health Journal Club, a forum for professionals to discuss academic papers as a way of keeping abreast of the literature, improving my decision-making skills and my critical appraisal skills, and as a way of retaining a critical awareness of health theories and methods used to promote health and prevent disease. I attend meetings and liaise with colleagues from appropriate professional networks locally and nationally in order to share best practice. Being part of a team has resulted in my developing valuable knowledge and skills.

In August 2010 I was selected for mentoring by the NHS institute for Innovation and Improvement's National Top Talent Programme and I was mentored by a development and talent consultant and executive coach. The 1:1 nature of the sessions meant that I could have a programme that focused exclusively on me as an individual, with the sole aim of my development. Mentoring took place over a twelve-month period and consisted of eight 1:1 sessions and six workshop sessions that were beneficial to my

continued professional development. Receiving the advice and wisdom of an individual with a different perspective on my professional and personal challenges, the sharing of thinking and experience, and having the time and space to reflect on my own assumptions and beliefs was an invaluable experience for me. It developed my interests, my knowledge and skills, and the support of my mentor and the NHS London team has considerably increased my confidence.

I attend conferences including those held by the Division of Health Psychology, UK National Smoking Cessation (UKNSCC), and Tobacco Control. I attend workshops and trainings days hosted by the British Research and Training in Health Psychology Initiative (BREATHE), the British Association for Behavioural and Cognitive Psychotherapies and City University (Professional Development Seminars). The importance of continued professional development (CPD) was strongly emphasised to all Stage 2 trainees during the first two years of training, during which time we received monthly training and development in all professional skills required of a Registered Practitioner Psychologist.

Regular supervision has been essential for the continual development of my practice. Raising issues, voicing challenges, gaining support and feedback has helped me to identify my strengths and weaknesses and continuously reflect upon, criticize and review my skills and knowledge. It has been a catalyst for my skill development and has consolidated my learning. I make use of the yearly Appraisal and Personal development plan within the workplace – this underpins the whole process of my professional development.

Provide psychological advice and guidance to others. I routinely provided psychological advice and guidance in the Stop Smoking Service's educational, promotional and motivational materials. Psychological advice contributions were provided online, via texts, telephone, leaflets and posters.

To demonstrate my learning and competence in this area, I discuss providing psychological advice and guidance in terms of my clinical and training and supervisory responsibilities.

Clinical responsibilities. The delivery of evidence-based smoking cessation advice to individuals utilising both psychological and pharmacological treatment approaches is central to my role as a practitioner psychologist within the smoking cessation field. I provide advice in individual (face-to-face) and group contexts within a structured program of activity over a period of seven weeks. Psychological and

behavioural management tools include motivational interviewing (Miller & Johnson, 2001) for client motivation to engage in long term behaviour change: interventions are matched to clients' readiness to change and influenced by the stages of change (DiClemente et al., 1991), theory of planned behaviour (Ajzen, 1985), and self-efficacy (Bandura, 1977) models. Additionally, a bio-psychosocial model of addiction is used where clients' beliefs about their smoking behaviour, social contexts and coping mechanisms are gauged. The main components of the intervention are cognitive behavioural therapy (CBT) and withdrawal-oriented therapy. I provide advice on the biological aspects of nicotine addiction and its interaction with psychological aspects of addiction. I also provide advice on relapse prevention.

Training and Supervisory Responsibilities

I provide on-going advice, education, guidance and support on the psychological component of treatments to HCP's during our training events and in monthly supervisory sessions. In order to reflect on and monitor my skills on giving psychological advice, I routinely look at my outcome reports (required by the DH) and those of the HCP's that I supervise. This serves to evaluate the impact of the advice given. The average 'Quit Rate' for individuals stopping smoking when being treated as part of a group is 65%. The average Quit Rate for individuals being treated one to one by a HCP (under my supervision) is 48%.

I have learnt that giving psychological advice and guidance is most effective when the recipients are motivated to receive and apply it and I now feel confident about engaging people in a process of examining the guidance and advice so it can be made meaningful and useful to them. I have benefitted from this approach enormously because as well as improving the quality of exchanges with my clients, I have learnt more about the broader significance of the advice and how it might apply to my own life and professional activities.

Provide feedback to clients. During my professional training I have routinely provided feedback to clients in managerial, supervisory, training/development, consultant and clinician roles where feedback is given in relation to individual's smoking cessation.

To demonstrate my learning and competence in this area, I discuss giving feedback to Trainees and HCP's for whom I have provided supervision.

Trainees. Trainees are assessed informally in both role play and a final question and answer session on the incorporation of counselling appropriate to the stages of change model (DiClemente et al., 1991), and adherence to the smoking cessation intervention protocol. Gaps in knowledge are subsequently addressed via feedback. Trainees are supported, encouraged and given appropriate feedback, and queries and problems are responded to as they arise. I am available during breaks for discussion and feedback as needed. Providing feedback has the potential to improve performance through reinforcement of good practice, correction of mistakes and the facilitation of professional development (Hawkins & Shohet, 2000).

Supervision post-training. I provide supervision and follow-up to trainees who need extra support. I give feedback on quarterly performance, clarify psychological issues and other aspects of the intervention that need addressing and give honest constructive feedback. I use methods put forward by Hawkins and Shohet (2000) where feedback involves a three-stage process: 1. they provide a self-assessment of their performance; 2. I praise what was done well; 3. I discuss constructively any errors made in the intervention protocol. In stage 3 my concern is to strike a balance between providing feedback in a timely fashion and providing feedback that can be absorbed and acted on, i.e. in order to avoid over-loading HCP's with a large number of issues, which may be discouraging and counter-productive, I prioritise three or four points and provide feedback sensitively on how to improve on these areas. Anything left out on a feedback session is picked up as soon as possible in future feedback sessions; the guiding logic is that understanding, and skill acquisition are most effective when a small number of behaviours are identified as being in need of change. HCP's are also encouraged to think reflectively about whether they found the session useful and what they felt they had achieved during the session. McClure (2005) argues that the supervisory relationship is key in assisting supervisees in becoming more reflective. This method has also proved useful in providing feedback for me and I have been able to improve my feedback giving skills. A culture of mutual positive regard has been engendered - this is evident from the warmth and positive non-verbal behaviours displayed, e.g. good levels of eye contact, smiles and head nodding. My confidence in giving feedback has grown considerably - mainly because it is clear that the approach is working and I have clear evidence of this in the form of individuals becoming competent advisors (evidenced by DH performance data).

Conclusion

Having started from a place of zero experience in applied health psychology, the route to competence has been both demanding and not without its challenges. As there was no one experienced available, I was 'thrown in at the deep end' at the beginning of my career and was expected to organise and lead a training event. A naturally quiet individual with more introvert characteristics than extravert, I found this challenging at the outset, i.e. I was not attracted to public speaking and lacked confidence. However, I have felt committed to training and development to such an extent that over a period of time I have developed an extensive range of skills that have enabled me to develop, organise and run bespoke training programmes to a wide variety of HCPs. My line manager praised my training during annual appraisals and has talked of getting it accredited. I have had the rewarding and gratifying experience of being recognised for my training by other parts of the Trust: examples include, 'Health First' the Trust's NHS specialists in health promotion. I am frequently recommended for training input and delivery. This has boosted my confidence significantly.

In addition, throughout my training through being given a wide variety of tasks spanning the roles of Family Health Advisor, Stop Smoking Advisor and Primary Care Facilitator, I have taken on several responsibilities which have increased my confidence and ability to take on new challenges, i.e. the line management of two staff members and the supervision of HCPs. Further skills consolidated during this time are the ability to develop, implement and manage interventions, research and evaluate interventions, carry out systematic reviews, carry out consultancy, write protocols, reports and guidelines. I now have the confidence to stand up in front of groups of people to deliver complex ideas clearly and simply (without jargon) at briefings and presentations. I have worked effectively with a wide variety of client populations and organisational cultures, and whilst liaising, networking and negotiating with these populations, I have developed interpersonal skills and a sensitivity to different perspectives. I continue to develop as a practitioner psychologist and trust that the above skills will stand me in good stead working in this area - I look forward to working as a chartered health psychologist in the near future. Throughout my career I have been committed to using my skills as a trainee practitioner health psychologist to address inequalities in health and have gained some understanding of barriers to reducing the impact of smoking in diverse populations and motivating individuals within these populations towards

behaviour change (Appendix A), and I have gained confidence in my ability to apply psychology to other relevant areas of health.

I left the Public Health Department after a total of 10-years continuous service, first in [redacted] PCT (2 years) and then in [redacted] PCT/ [redacted] (8 years); when I left [redacted], The Director of Public Health wrote a reference for me in which he described me as an 'adept researcher' and my academic input as 'particularly notable' (Appendix A). I left on [redacted] in order to pursue freelance work and I have worked part time since then while continuing to work on my research and consultancy competencies. I have developed my consultancy and research competencies by way of a professional relationship I have established with a London based firm of occupational psychologists where I have been engaged in carrying out a systematic review on mindfulness, helping the firm inform practice on mindfulness for work they are doing within organisations and with disabled individuals. In conclusion, upon reflection, my journey to Registered status has been a challenging and enjoyable experience, and I am very grateful for the skills, knowledge and experiences gained. I truly appreciate my accomplishments and I feel a great sense of achievement.

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Appendices for Generic Professional

Appendix A

Contact [redacted]
Telephone [redacted]
Facsimile 020 8 -
Email [redacted]

Public Health Department
Adults and Older People's Services
[redacted]

Main number [redacted]
Textphone -

To whom it may concern,

RE: Reference for [redacted]

[redacted] worked as a valued member of the stop smoking team in [redacted] for eight years.

Her academic input was particularly notable as was the quality of her training with health professionals, such as nurses, pharmacists and care assistants.

She worked on a number of processes, which remain in active use by our team, such as PowerPoint presentations for Level 2 stop smoking training.

[redacted] was committed to improving health outcomes across the borough and was an adept researcher, for example when transposing national guidelines into local practice.

We wish her well for the future.

Yours faithfully,

[redacted]

Director of Public Health

Core Unit 3: Consultancy Case Study

Setting: [redacted] PCT Department of Public Health

Background to Consultancy Request

In July 2004 I was contacted by a representative of the [redacted] Research Unit about the feasibility of providing consultancy for the [redacted] Primary Care Trust (PCT) Neighbourhood 2 Manager (the client). The client wanted to provide proof that the NHS Acupuncture service in the borough was cost-effective as that service would be reviewed with Practice Based Commissioning (PBC) responsible for funding and she wanted to ensure continued provision of that service. My role within the Department of Public Health was Stop Smoking Service Facilitator. I was approached by the client because she knew that I was a trainee health psychologist with an interest in acupuncture.

Assessment of Request for Consultancy

I conducted an initial telephone interview with the client (7/7/04) in order to acquire a broader understanding of the context of the consultancy and to assess the feasibility of my undertaking the consultancy project. The scope of this interview included examining the client's needs and expectations regarding the consultancy as well as critical influences that might be affecting the consultancy itself (see Consultancy Appendices; Appendix A).

In the course of the telephone exchange with the client I was provided with information about the context of the project under consideration. I was told that a pilot acupuncture service had been set up in January 2001 with the objective of enabling PBC to make an informed decision on its continued provision.

The acupuncture service operated within referral protocols and arrangements for access for patients from practices within a geographically defined locality was based on practice location and patient population.

The client believed that the service was received very positively by patients and she was therefore determined that it should continue in relation to which she explained that she would need:

- *A survey of GP's use and views of the Service.*

- *An assessment of cost effectiveness, i.e. in terms of either a reduction in patients smoking or linked in some way to reduced prescribing.*

To further assess the feasibility of the project I arranged an initial meeting to include the client, the LRU representative, my line manager and myself. This meeting took place on 9th August 2004. We looked at what an assessment of cost effectiveness might involve, appropriate outcome measures, personnel to be involved in the evaluation and we discussed the feasibility of my carrying out the consultancy. We also discussed possible constraints facing the consultancy including the issue of my time commitment to the project, i.e. I was in full time employment working for the Smoking Cessation Team within the Public Health Department in the PCT and the project had to be completed within a year. The LRU representative offered the possibility of funding the consultancy under 'evaluating innovation' or 'patient experience' but my manager suggested that I could carry out the project within my existing remit as it had a smoking cessation element. The consensus was that the Public Health Department needed the work done anyway and given the fact that I worked within that department it seemed logical and acceptable for me to offer consultancy. It was agreed that I would review the appropriate literature and feedback to the client my conclusions as to the feasibility of the project.

Based on information I collected in telephone interviews with the Acupuncturists (11.8.04), examination of relevant literature and an informal conversation with The Director of Public Health (DPH) I concluded that it would not be feasible to carry out an assessment of cost effectiveness based on patients stopping smoking. My reasoning was based on (compelling) evidence, i.e. an examination of the literature had identified a systematic review that concluded that there was no evidence that acupuncture had an effect on either withdrawal symptoms or smoking cessation (White, Rampes and Ernst, 2002). In addition, the National Institute of Clinical Excellence (NICE) which guides NHS decision-making and makes recommendations based on appraisal of the clinical effectiveness and the cost effectiveness of new and established technologies found there to be no evidence base for acupuncture's efficacy in smoking cessation (NICE Guidelines,2004); second, it was clear that the Acupuncturists did not routinely ask patients about their smoking status and very rarely treated smoking cessation, and third, the DPH was not in favour of the project as he was 'anti-acupuncture' due to its lack of evidence base.

I fed back the above-mentioned findings to the client and the LRU representative (Consultancy Appendix A) and we decided that a way forward could be to look at cost-effectiveness of the acupuncture service with regards to reduced prescribing.

The client decided to re-negotiate the terms of our consultancy contract i.e. she requested that the consultancy be externally validated by City University; her motivation in this respect was in a large part due to the skepticism expressed by the Director of Public Health (DPH) in relation to acupuncture, i.e. the client felt that in view of the DPH's opinions it was wise to involve City University in order to enhance the credibility of the consultancy.

Due to the refinements to the aim of the consultancy It was necessary to examine the literature concerning cost effectiveness, cost benefit or cost comparison of acupuncture and orthodox medicine and prescribing. I searched Medline, Embase and AMED electronic databases. Research findings indicated that possible (outcome measures) areas to be considered for cost savings with acupuncture include a reduced need for drugs, a reduced need for referral for secondary care and reduced costs of adverse effects of other orthodox treatments.

Reflection

Being relatively new to my role in the public health department, I was happy that I was targeted to take on this consultancy role, and I found the topic especially interesting as complementary alternative therapies are a particular area of interest for me. I was looking forward to having a new experience of working with another department and I was excited to be gaining skills in this new area of competence. I was a little disappointed to not be getting paid separately for the work and to not have had a better experience of fee negotiation as I thought that it would make me more of 'a real consultant'. Being new to the department and being so grateful for the opportunity I did act assertively in stating my preference this is an area in which I need to build confidence; however, this is my first experience and I felt sure that I would get better in this area. I was happy to have a proper contract for my services.

Another challenge for me was the client informing me that she now wanted the consultancy to be externally validated by City University; her motivation in this respect was in a large part due to the skepticism expressed by the Director of Public Health (DPH) in relation to acupuncture generally and its effectiveness as a procedure in

smoking cessation specifically, i.e. the client felt that in view of the DPH's opinions it was wise to involve City University in order to enhance the credibility of the consultancy. This requirement caused considerable delay to the consultancy process which seemed to lose some momentum.

With the benefit of hind-sight I realise that it would have been better if I had uncovered and explored these power and influence issues at the initial stage as it had a very major impact on the client. I found this challenging because at this late point I felt the need to explore to what extent 'the contact client' had sufficient power and influence to secure the consultancy in any form. According to Earll and Bath (2004) (identifying the client) can be ambiguous and problematical; Schein (1999) identifies 6 types of client and using his classifications (in italics) I identify below the clients for the consultancy project.

Contact client. The LRU representative & the Manager of The Acupuncture Service Intermediate Clients- The Acupuncturists that provide the Service.

Primary client. The Acupuncture Service who own the problem of service provision.

Unwitting clients. Staff of the PCT whose patients would benefit from the service & colleagues of the Acupuncture Service personnel.

Ultimate Clients. The residents of the borough that would benefit from the service

Involved non-clients. the PCT and (PCG)/Clinical Governance who may have conflicting goals i.e. trying to reduce spending and reduce the financial debt of the PCT.

It was also necessary to identify the 'Sponsor' of the consultancy in this case the sponsor was 'the client' (the Manager of the Acupuncture Service)

Planning Consultancy (3.2)

After the initial assessment of the request had been completed I started to plan the work and to negotiate with the client the terms of the consultancy contract. I convened a meeting with the client, Professor [redacted], and myself on 16th December 2004 where I presented my findings and recommendations regarding the proposed consultancy based on examination of the literature and discussions with others in relation to the project. I confirmed the feasibility of the project and recommended that I: (1) devise and analyse a survey of GP's views and usage of the acupuncture service; and, (2) be provided with patient discharge forms with a view to providing analysis that

would inform the client on usage of the service, treatment outcomes and cost-effectiveness. Cost efficacy was to be based on reduction in the need for drugs and reduction in the need for further referral to other services. See Table 1 for the aims and objectives of the consultancy.

The evaluation criteria and terms of the contract were discussed. The client wanted the project to be completed within a year of the date of this meeting (December 2005).

TABLE 1: Consultancy aims and objectives

Aim:

To conduct a survey of usage of the [redacted] PCT Acupuncture Service & provide data & analysis in relation to its utility & cost effectiveness

Objectives:

1. To assess GP awareness of the Acupuncture Service.
2. To assess the extent to which GP's understand & are making use (or intend to make use) of the Acupuncture Service.
3. To assess GP satisfaction with the Acupuncture Service.
4. To assess the perceived cost-effectiveness of the Acupuncture Service.
5. To assess the cost-effectiveness of the Acupuncture Service using reduced prescribing and reduced referrals for secondary care and other services.

It was agreed that my role would include: devising a questionnaire; collecting and analysing the survey data; analysing patient discharge forms, i.e. those detailing prescribing; and, the production of a report to be submitted to the client. A number of practical issues were also resolved (Consultancy Appendix A).

Theoretical Basis of Consultancy

The Process Consultancy Model (PCM) (Schein, 1999) was adopted in the initial enquiry stage; in this model the client explains the issue and the consultant seeks to understand it and strives to work with the client. The aim of the PCM is to provide a helpful way of examining the issue and a helpful course of action. PCM involves sharing and caring about the problem but ultimately not 'owning' it; the approach requires: listening, learning, analysing, reflecting and empathising. The PCM approach has the potential to enable the client to make effective progress on the issue. Schein (1999) suggests that a consultancy should always begin in the PCM mode before deciding whether it's desirable to move into another consultancy mode.

The dynamics of this consultancy required the mode of consultancy to continually shift. Schein (1999) states that the mode of consultancy needs to be flexible. I had to be conscious of which role I wanted to be in from one moment to the next i.e. which would be most helpful to the client at any given time.

I also used the 'Expert' model of consultancy, which Schein (1999) describes as the client defining a need or problem and purchasing from the consultant information or an expert service that they are unable to provide themselves. In this case the client was purchasing health psychology expertise and statistical analysis skills in order to gain information regarding (1) the acupuncture service's standing (2) GP and patient satisfaction and (3) cost-effectiveness, according to Schein this model 'assumes that the client knows what kind of information or service she or he is looking for and that the consultant is able to provide the information' (Schein 1999).

At the end of the consultancy the 'Doctor-Patient' model was employed. This model is an elaboration of the 'expert' model, the additional component being to make a diagnosis and recommend what kind of information would solve the problem. In this case the diagnosis was the discharge form was inadequate and would need to be redesigned and recommendations for its design were provided.

The next stage was the drawing up of the Implementation Plan (Consultancy Appendix B)

Reflection on Planning Consultancy

The initial planning of the consultancy went very smoothly. The client really took 'a step back' and left me to get on with developing and maintaining the project. It really was the client 'buying' my expertise so the expert model was a really appropriate one. I enjoyed this initially because the work felt like my project, but later I found this situation overwhelming when I had my 'normal' work to do as my line manager had quickly lost interest in the project. It was therefore becoming increasingly difficult to incorporate this work into my day to day time spent carrying out my smoking cessation role. I had to re-consider how I was going to work with this. Earl and Bath (2004) argue that essential skills consultants should acquire are time management capabilities, financial skills, effective listening and communication skills in order that one can undertake and deliver projects in the right time frame. I spoke with my manager and gently reminded her that in addition to my regular duties I needed to allocate time to this project and I reflected on how I could make more effective use of my time.

Establish, Develop and Maintain Working Relationship with Client (3.3)

Key Personnel

i.Acupuncture Service Manager

ii. Acupuncturists

Throughout the consultancy I ensured that the lines of communication with key personnel remained open. Communication was enabled via telephone, meetings and email. (Consultancy Appendix A)

Acupuncture Service Manager

Initial meetings served to provide information regarding the clients perceived needs and expectations, they looked at what the evaluation might incorporate; outcome measures to be used, personnel to be involved in the evaluation and issues around contracting etc (Consultancy Appendix A). The opportunity to meet and plan prior to the start of the consultancy helped clarify roles, build relationships and establish the working approach. A written contract was devised in order to clarify understanding before the project began; this served as a written agreement of mutual expectations (Consultancy Appendix C). I ensured that it detailed the form of the consultancy; boundaries of my role; compensation; objectives of the project; specified resources; required client support; time schedule and issues of confidentiality.

Meetings and the informal feedback procedure that I established were the main instrument for establishing and maintaining a working relationship with the client (Consultancy Appendix A). The informal feedback procedure (telephone conversations, face-to-face meetings and emails) involved regular reviews by myself and details of any concerns I had regarding administrative matters as well as eliciting client input on various matters. It also enabled discussions of the evaluation criteria for the consultancy and provided an opportunity for the client to raise concerns and feedback on documents, reports and the issues regarding the development of the survey.

Taking any concerns into account I progressed discussions until consensus was reached. For example, the Service Manager was concerned with the length of the survey and in acknowledging her concerns I provided clarification i.e. that any one GP would only complete half of the questionnaire (i.e. the half pertaining to them). I subsequently reduced its length and further clarified the instructions.

Acupuncturists

Maintaining positive relationships with the Acupuncturists was important because they provided valuable input into the work. To inform the design of the Survey I needed to: understand collated information on patient forms; negotiate access to patient notes to ascertain reduced prescribing from the discharge form; and, ask questions regarding the GPs.

Initial contact was made on August 11th 2004 and then at various points throughout the consultancy as and when needed; communication was maintained via telephone calls and meetings (Consultancy appendix A).

Discussions involved introducing myself and the work that was to be undertaken and gathering information regarding patient consultations that were relevant to the design of the project. I provided opportunity for them to raise concerns and provide feedback on aspects of the work being undertaken. It became clear that the Acupuncturists did not routinely ask patients about their smoking status and that they very rarely treated patients to help them quit smoking. Accordingly, I advised my client that it would not be feasible to carry out an assessment of cost effectiveness based on patients stopping smoking.

Conducting the Consultancy (3.4)

Questionnaire Development & Data Collection

I designed an 'attitude' survey to access GP's current feelings and opinions towards the Acupuncture Service (Consultancy Appendix D). The questions were designed in relation to the topics of interest identified in the aims and objectives of the work to be undertaken as this would make it easier to analyse for validity. The content areas were agreed by the LRU, the client and I, and the questions were designed and developed in line with relevant questions from similar surveys, (i.e. those designed with a similar purpose in mind) conducted within national and local PCT's, the questions were screened for relevance and where appropriate were improved/amended.
Once I had collated the appropriate questions I developed the response formats. Questions consisted of a combination of predetermined responses (as I needed it to provide quantifiable data that could be statistically manipulated to reflect GP's attitude towards the service) and open-ended questions to elicit broader response data in relation to the aims of the study. Spaces were left for verbatim comments and respondents were asked to record any additional comments

After ensuring that the questions were neither 'loaded' or 'leading' and not subject to 'response set', i.e. by using a varied response scale, I liaised with the client and Professor [redacted] regarding feedback on the questions. In addition, I ensured that questions were printed clearly and professionally and were easy to comprehend and that the filter questions were clearly labelled i.e. so that it was clear which question to go to next. I also wrote a brief introduction and instructions for respondents (placed at the beginning) and a courtesy 'Thank You' and section with my contact details.
In order to assess the appropriateness and acceptability of the questionnaire the questionnaire was piloted on a local GP with an interest in the research. I ensured that the strategy for dealing with and minimising poor compliance was in place i.e. The Manager was to engage with GP's prior to survey distribution. I then liaised with the Administrators to ensure that the questionnaires went out complete with: a covering letter that provided the necessary introductions (i.e. introducing the personnel involved); contact details; the purpose of the survey and the contact address. Surveys were sent to the entire GP population in [redacted] (103 / GP's) via email. Surveys were completed and returned although the response yield was very disappointing 9/7% (n=10).

Data Collection & Data Inputting of Patient Discharge Forms

Acupuncturists had the patient discharge forms ready for me to collect by June 27th 2005. I collected data on all patients (from 2004 -2005). Due to the other Acupuncturist being unwell, I went to the Surgery of the 3rd Acupuncturist on June 27th 2005 and personally copied the files. All data collection was done in line with the Calldercott (1997) general principles for health and social care organisations regarding client information.

Unfortunately, I sustained an arm injury that rendered me unable to immediately input the data i.e. (1) The survey of GP's views on the service; and, (2) The discharge forms completed by acupuncturists at cessation of treatment. This delayed the work, however, the data was subsequently inputted, analysed with help from an MSc. student and a report was sent to the client on December 1st 2005. Due to problems with the design of the discharge form (i.e. it was too vague in relation to changes in prescribing and did not include the nature and dosage of medication before and after treatment as initially stated) the data was not sufficiently robust enough to carry out a fully comprehensive economic evaluation of the acupuncture services' cost-effectiveness.

Reflection

In many respects, conducting this consultancy was a steep learning curve for me and I have had had to learn from the many challenges that I have had within the consultation process. Firstly, upon reflection, at times I should have taken charge of the process better i.e. my reliance on the client for using what she described as an 'influential relationship' to enhance the response rate from GP's was poorly placed given the low response rate that resulted. It would have perhaps been better to have conducted the GP surveys by telephone or incentivised them in some way, perhaps by offering them payment to complete and return the survey. Research by Berry & Kanouse (1987) suggests monetary incentives do produce results in this area, these researchers report the result of an experiment in obtaining doctors response to a postal survey; of the two groups of doctors looked at, i.e. those who received payment and those who did not, it was the incentivised Dr's who had more significant positive response rates. As it is the culture within the PCT to incentivise practices generally for data returns this would perhaps have been a better alternative.

Closure of Consultancy

Monitor the process of Consultancy 3.5

The consultancy was monitored both in terms of reviewing the work to be undertaken and the accommodation of the client's needs and expectations throughout the project, which involved incorporating a continual review procedure into the process. It involved my working collaboratively, giving updates, asking for feedback and being flexible whilst working within the agreed plan of action, time frame and resources.

There were many times where flexibility needed to be incorporated into the consultancy process. It was not a linear process and things did not proceed as smoothly as I had hoped. For example, we had to change directions (after having done significant work e.g. meetings, telephone calls and research) with regards to its being a cost effectiveness evaluation from smoking cessation angle to reduced prescribing and this resulted in my having to actively manage the expectations of the client (as well as my own expectations). Continual monitoring and flexibility was needed throughout the consultancy process; I worked in a collaborative way throughout the project providing the client with regular updates. Regular mutual feedback was an essential component of the consultancy, particularly as there were some organisational changes i.e. changes in key staff with whom collaborative planning had been completed; specifically, the LRU

representative and my own line manager, both important supporters of the project, left their posts duriung the project.

My new line manager offered no support to me with regards to time for the projects' completion because this work was not on her agenda and I therefore had to complete it in my own time, which hindered progress with the project. As an internal consultant I was embedded in the current politics of an organisation, I had a line manager to satisfy and I was working within a different department with its own specific goals to achieve. I learnt that flexibility is needed in consultancy because there are bound to be changing demands and agendas that interfere with expectations. I found providing consultancy in this way challenging; however, I continued to work collaboratively, the process was flexible and I was still working within the agreed plan of action. Shein (1987) argues that successful consultancy requires the setting aside of expectations and I experienced this 'first-hand' – I was continually working to do this. Once the work was completed the final report was emailed to the client for her perusal and feedback (Consultancy Appendix E).

Evaluate the Impact of Consultancy (3.6)

The evaluation criteria for the consultancy was discussed and agreed at the initial planning stage of the consultancy in the meeting that took place on December 1st 2004.

It was ascertained that the consultancy would increase both the awareness of the acupuncture service in [redacted] and the number of GP referrals to the service as well as contributing to the planning and targeting of resources (and the procurement of additional resources).

The consultancy was evaluated via an informal discussion which took place on June 6th 2006; the perceived benefits of the consultancy were:

- The Acupuncture Service had the opportunity to receive meaningful and useful interpretations of the service they provide;
- The consultancy directly resulted in an increased awareness and understanding of the service provision amongst local GP's; and,
- Increased referrals to the service which resulted in the acupuncturists having a waiting list.

The report helped to illustrate the benefits of the service at the PBC review meeting and there was overall agreement from the PBC group on the benefits of the service in terms of the health benefits to patients in the borough and cost savings, (they took the GP's positive endorsements of the Service provision for patients, the cost effectiveness of acupuncture in terms of reduced prescribing and reduced referral to specialists/secondary care into account alongside the findings in the report that indicated reduction in patient medication as a result of treatment).

The outcome of the meeting was positive, e.g. the service was to continue. The service had started using the newly devised discharge forms in order for a full-scale evaluation to be done at a future date.

Reflection on Conducting Consultancy

This consultancy project fits well with the process consultation theory in that it resulted in helping the client improve the service in the future by providing them with suitable tools to improve the service (Schein, 1999). The client was happy with the consultancy and I felt a great deal of satisfaction in helping the service in this way. It was my first consultancy experience and I learnt a great deal from it; I lacked confidence initially and was not forthcoming enough at certain points in the process, e.g. I took the client at her word believing that the information needed was routinely gathered by the service and I neglected to voice my ideas about increasing GP engagement because the client had said that she had influence in that area, these 'errors' have raised my awareness of how important it is to check all the information provided at outset and this learning experience makes me better equipped for future consultancy work, e.g. I feel comfortable with being more assertive about my ideas in future consultancy work.

Conclusion

On reflection, although it was a very beneficial learning experience, I feel that I may have benefitted more from an external consultancy as I would have benefitted from the contract negotiation aspect and I perhaps would have felt more authority. In this consultancy I did not get paid and I had to do much of the work in my own time. i.e. because the resource of time was not available to me due to changes within the organisation. I continued with the project because I need to develop my skills in the

area and because I was interested in helping a service which I feel is very valuable to the community and I certainly beneffitted from doing so.

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Consultancy Appendices

Appendix A (page 1 of 4)

Consultancy: Contact Log

RE: Project: To survey GP use & views of acupuncture service and look at service cost-effectiveness

SE - Consultant,
LRU – Contact Client,
CG-Primary Client

Date	Form	Outcome
1/7/04	Telephone Contact (TC)	LRU invited SE to provide consultancy on the project. Needs and expectations discussed. Call to ascertain my interest in project
7/7/04	TC	Initial TC to acquire broader understanding of context of consultancy Pilot service in GP practices in 4 Neighbourhoods within borough based on GP referrals objective to enable PBC to make informed decision on its continued provision
9/8/04	Meeting	SE, Line manager, CC, PC Brainstorm session regarding feasibility of my carrying out consultation in consultation with my line manager. Ways of incorporating everyone's agendas into the consultancy in order that everyone's needs met, possibility of funding, possible constraints, possible outcome measures. No firm conclusions drawn. Action: research and consult acupuncturists to determine what was feasible. Report back as to feasibility of project. Next meeting TBC.
11/8/04	TC	Initial contact acupuncturists involved in project Determined that they did not routinely ask patients about their smoking status and very rarely treated smoking cessation
13/8/04	TC	TC with GP that CC recommended I meet with that had done a Cost effectiveness research with homeopathy. Meeting arranged for 19/8/04
19/8/04	TC	TC GP cancelled the meeting
9/9/04	Meeting	Met with GP that CC recommended who had previously done a Cost effectiveness research with homeopathy. Discussed her research to get ideas for consultancy.
16/9/04	TC	TC with PC re research into feasibility next meeting date to be organised to include City University Professor: Get a date
24/9/04	TC	TC with CC re research into feasibility next meeting date to be organised to include City University Professor: Get a date
30/09/04	Email	CITY to organise date to meet to explain consultancy

14/10/04	Meeting	Meeting at City to discuss consultancy project. Informed him about all details of PC requirements. University agreement procured. Get dates arranged for meeting with all parties involved. Talked about my getting consultancy contract and issues around consultancy.
28/10/04	Meeting	Meeting with PC to sign a contract and negotiate meeting and dates with University. PC will be on leave for 3 weeks so arrange upon return.
1/11/04	Meeting	PC sign consultancy contract. Next meeting TBC
25/11/04	Email	Procure meeting time and date for PC and University to meet in order to feedback and negotiate time with university
2/12/04	Email	University to negotiate date for meeting between all parties
16/12/04	Meeting	SE, University Professor and PC. PC Discussed background context to why the project needs to be carried out, aims and objectives, request for university involvement so project externally validated, increased credibility. PC would like to determine GP's perspectives on acupuncture service (e.g. if they are aware of service, if they refer and why, their perceptions of advantages of service, do they save money on drugs? appointment times? etc.) Survey required. Survey questions and distribution letter to be devised by me. PC to provide admin support of her team. PCT surveys usually get response rates of 40% and PC advised that she was very influential in terms of increasing response rates and would use her influence to increase response rates. Discussed my meetings with others on similar projects, the cost-effectiveness literature. I was Informed that acupuncture service patient records have details of medications before and after treatment and that this can be used to look at cost effectiveness. Confidentiality and storage of medical records discussed, resources and constraints of consultancy discussed (mainly my time), payment for consultancy discussed – I would provide consultancy free of charge as it would be part of my training. Consultancy contract discussed, evaluation report to be sent in a year. Contact details exchanged reporting and feedback and monitoring etc. Next meeting TBC
21/01/05		Presented and Discussed rough monthly timeline/ implementation plan with university.

17/02/05	Email	budget holder for service emailed to ask for costs involved with the service
28/02/05	TC	Called Acupuncturist A for further detail on costs
8/03/05	TC	Called Acupuncturist B for further detail on costs
17/03/05	TC	Called Acupuncturist C &D for further detail on costs
01/04/05	Email	Emailed professor tentative questions and negotiated time to meet to look at questions and survey design.
11/04/05	Meeting	Meeting at university to discuss questionnaire
18/04/05	TC & email	Called PC's admin to talk about survey and emailed questionnaire and cover letter for PC to examine.
20/4/05	TC	TC with PC to agree questionnaire and its distribution. Supportive conversation around Discussed organisational changes impacting consultancy progress.
16/05/05	TC	PC's admin to chase-up survey non-responders
03/06/05	TC	Called acupuncturists to arrange to get patient records
8/06/05	Meeting	Met with acupuncturist C to get patient files
10/06/05	Meeting	Met with acupuncturist A for files
14/06/05	Meeting	Obtained files from acupuncturist B
27/06/05	Meeting	Met with acupuncturist D to get files
8/07/05	TC	PC to inform her of poor response rate to questionnaire and gain her input/feedback on expectations and plan how to move forward
16/08/05	Email	To arrange meeting with professor for questions about/to take initial look at all data
14/09/05	TC	Updated PC on progress. Informed of injury to arm that was delaying data inputting progress and strategy put in place to meet deadline
28/09/05	Meeting	Met with University Professor and MSc student. Talked about data inputting, analysing data and project deadline. Next meeting TBC
10/11/05	Meeting	Met with MSc student re data
1/12/05	Email	Emailed report and recommendations
6/12/05	TC	Follow up call to PC to discuss report and way forward
6/06/2006	Meeting	Met PC, discussed recommendations and whether and how these were taken forward. Discussed perceived benefits of consultancy.

28/09/05	Meeting	Met with University Professor and MSc student. Talked about data inputting, analysing data and project deadline. Next meeting TBC
10/11/05	Meeting	Met with MSc student re data
1/12/05	Email	Emailed report and recommendations
6/12/05	TC	Follow up call to PC to discuss report and way forward
6/06/2006	Meeting	Met PC, discussed recommendations and whether and how these were taken forward. Discussed perceived benefits of consultancy.

Appendix B (page 1 of 7)

PERIOD: ONE YEAR

Name: [redacted] [redacted]

Implementation Plan

Evaluation of Acupuncture Services [redacted] PCT: Cost effectiveness

Objective 1: To evaluate GP's awareness of the Acupuncture Service		
Implementation Plan	**Action Required to Progress Plan**	**Implementation Schedule**
• Devise relevant question on questionnaire.	• Seek advice from supervisor on designing the questionnaire, look into relevant literature for service evaluation studies and relevant questions to evaluate this item.	• April 2005
• Distribute questionnaire to GP's		• April 2005
• Follow up non-responders		• May 2005
• Collect data		• May 2005
• Collate data		• May 2005
• Analyse data		• June 2005

Objective 2: To evaluate to what extent GP's are making use (or intend to make use) of the Acupuncture Service		
Implementation Plan	**Action Required to Progress Plan**	**Implementation Schedule**
• Devise relevant question on questionnaire.	• Seek advice from supervisor on designing the questionnaire, look into relevant literature for service evaluation studies and relevant questions to evaluate this item.	• April 2005
• Distribute questionnaire to GP's		• April 2005
• Follow up non-responders		• May 2005
• Collect data		• May 2005
• Collate data		• May 2005
• Analyse data		• June 2005

Objective 3: To evaluate GP's satisfaction with the Acupuncture Service.

Implementation Plan	Action Required to Progress Plan	Implementation Schedule
• Devise relevant question on questionnaire.	Seek advice from supervisor on designing the questionnaire, look into relevant literature for service evaluation studies and relevant questions to evaluate this item. Seek advice from supervisor on designing the questionnaire, look into relevant literature for service evaluation studies and relevant questions to evaluate this item.	• April 2005
• Distribute questionnaire to GP's		• April 2005
• Follow up non-responders		• May 2005
• Collect data		• May 2005
• Collate data		• May 2005
• Analyse data		• June 2005

1. **Objective 4:** To evaluate the perceived cost-effectiveness of the Acupuncture Service.

Implementation Plan	Action Required to Progress Plan	Implementation Schedule
• Devise relevant question on questionnaire.	Seek advice from supervisor on designing the questionnaire, look into relevant literature for service evaluation studies and relevant questions to evaluate this item. Seek advice from supervisor on designing the questionnaire, look into relevant literature for service evaluation studies and relevant questions to evaluate this item.	• April 2005
• Distribute questionnaire to GP's		• April 2005
• Follow up non-responders		• May 2005
• Collect data		• May 2005
• Collate data		• May 2005
• Analyse data		• June 2005

Objective 5: Use patient information to evaluate levels of medication pre-treatment & after treatment to determine if there was a reduction in medication after being treated by the Acupuncture Service.		
Implementation Plan	**Action Required to Progress Plan**	**Implementation Schedule**
• Obtain patient records from Acupuncturists at the 4 Health Centres offering Acupuncture Services.	• Visit the Health Centres to obtain patient information & collate data	• May/June 2005
• Analyse Data	• Meet Professor Nancy Devlin Department of Economics city University for advice on health economics	• June 2005
	• & conduct data analysis	• July 2005

Appendix C

Appendix C

City University London

[redacted] NHS

Primary Care Trust

Consultancy Contract

1st November 2004

Dear Chris,

Further to our meeting on 28th October 2004, I am writing to confirm that we have agreed that I will carry out an evaluation of the [redacted] Acupuncture Service. This will involve my designing a questionnaire for GP's in [redacted] aimed at gauging their awareness of the service and getting their opinions about it. We have agreed that you will distribute the questionnaire to GP's and that you will provide me with access to patient records held by the Acupuncture Service. It is planned that the project be completed within one year whereupon I will submit a report to you.

If you are happy to agree to the above, please sign and return this letter to me, to confirm your agreement. I enclose two copies of the letter so that you also have a copy for your records.

Yours Sincerely,

[redacted]

Signed: [redacted]

Signed: [redacted]

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Appendix D (page 1 of 6)

[redacted] NHS
Primary Care Trust

Survey of local general practitioners' utility of the [redacted] Care Trust Acupuncture Services

[redacted]rimary Care Trust Acupuncture Services

Acupuncture is available for [redacted] residents by GP referral. The service is managed by [redacted], Neighbourhood 2 Manager.

Examples of the types of problems appropriate for acupuncture are: pain and stiffness of neck, shoulder, chest, back, hip, muscular, joint and soft tissue. Acute and localised pain e.g. sciatica, facial pain, neuralgia, headaches, migraines, Dysmenorrhoea and pre-menstrual syndrome, abdominal pain including irritable bowel syndrome, nausea and vomiting, anxiety and stress related conditions, insomnia and other sleep disorders, chronic fatigue e.g. lethargy, tiredness & exhaustion, Dyspepsia and skin disorders e.g. Eczema and psoriasis.

The Service is available at the following Health Centres:

The [redacted] Medical Centre, [redacted]
Wed 9am-12 noon & Thurs 3pm-6pm
Tel: [redacted]

[redacted] Medical Centre, [redacted]
Tues 8am-2pm
Tel: [redacted]

[redacted] Health Centre, [redacted]
Wed 9.15am-3pm
Tel: [redacted]

[redacted]
Tues & Thur 2pm-5pm
Tel: [redacted]

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(1) Were you aware of the [redacted] Primary Care Trust Acupuncture Services? Please circle the appropriate response.

Yes/No

(2) Do you refer into [redacted] Primary Care Trust Acupuncture Services ? Please circle the appropriate response.

Yes No

If Yes please complete **Section B** if No please complete **Section A**

Section A

(3) What are your views on the Acupuncture Service provided by [redacted] PCT?

Comments.....
.....
.....

(4) Do you think the Acupuncture Service could be of benefit to your patients?

Comments.....
.....
.....

(5) Could the Acupuncture Service contribute any of the following? Please circle the appropriate response.

Reduction in medication	yes/no
Improved psychosocial care	yes/no
Reduced referrals for specialist treatment	yes/no
Care for chronic conditions including pain	yes/no

Any other ways in which the Acupuncture Service could be of help?

Comments.....
.....
.....

(6) Would you consider referring a smoker into [redacted] PCT Acupuncture Services for Smoking Cessation? Please circle the appropriate response.

Yes/No

(1) Were you aware of the [redacted] Primary Care Trust Acupuncture Services? Please circle the appropriate response.

Yes/No

(2) Do you refer into [redacted] Primary Care Trust Acupuncture Services ? Please circle the appropriate response.

Yes No

If Yes please complete **Section B** if No please complete **Section A**

Section A

(3) What are your views on the Acupuncture Service provided by [redacted] PCT?

Comments.....
.....
.....

(4) Do you think the Acupuncture Service could be of benefit to your patients?

Comments.....
.....
.....

(5) Could the Acupuncture Service contribute any of the following? Please circle the appropriate response.

Reduction in medication	yes/no
Improved psychosocial care	yes/no
Reduced referrals for specialist treatment	yes/no
Care for chronic conditions including pain	yes/no

Any other ways in which the Acupuncture Service could be of help?

Comments.....
.....
.....

(6) Would you consider referring a smoker into [redacted] PCT Acupuncture Services for Smoking Cessation? Please circle the appropriate response.

Yes/No

(7) Acupuncturists give lifestyle advice as part of the treatment to patients. Would you consider referring patients who might benefit from health promotion /disease prevention into the service? Please circle the appropriate response.

Yes/No

(8) Now that you are aware of the service will you consider referring patients into the service? Please circle the appropriate response.

Yes/ No

Comments.....
.....
.....

Thank You For Completing This Questionnaire

Please return to: [redacted] Primary Care Facilitator, Public Health Department, [redacted]

Section B

(9) What criteria do you use when considering a patient for referral into [redacted] PCT Acupuncture Services?

Comments.....
.....
.....
.....

(10) Do you refer patients into the sole care of the Acupuncture practitioners or do you continue to see patients simultaneously?

Comments.....
.....
.....
.....

(11) How does the Acupuncture Service benefit your patients?

Comments.....
.....
.....

(12) Does the Acupuncture Service contribute any of the following? Please circle the appropriate response.

Reduction in medication	yes/no
Improved psychosocial care	yes/no
Reduced referrals for specialist treatment	yes/no
Care for chronic conditions including pain	yes/no

Any other ways in which the Acupuncture Service can be of help?

Comments.....
.....
.....

(13)Where do you see the most gain to patients that you refer into [redacted] Acupuncture Services?

Comments.....
.....
.....
.....

(11) Acupuncturists give lifestyle advice as part of the treatment to patients would you consider referring patients who might benefit from health promotion /disease prevention into the service?

Comments.....
.....
.....
.....

(12) Would you consider referring a smoker into [redacted] Acupuncture Services for Smoking Cessation? Please Circle your response.

Yes/ No

(13)Are you satisfied with the Acupuncture Services provided to your patients by [redacted] ? Please Circle your response.

Yes / No

Comments.....
.....
.....
.....

(14) Have you ever had to refer patients to local Acupuncturists in private practice because of lengthy waiting lists for the [redacted] PCT Acupuncture Services?

Comments.....
.....
.....
.....

Thank You For Completing This Questionnaire

Appendix E (page 1 of 5)

An Analysis of Outcome Data – A Brief Report.

A brief report by [redacted]

City University, London

1. Introduction

This preliminary report briefly sets out the findings of an evaluation of the acupuncture service.

2. Methods

The study is in two parts: (i) a survey of GPs' views on the service; (ii) an analysis of the discharge forms completed by acupuncturists at cessation of treatment.

(i) GP survey

103 GPs were sent a brief questionnaire seeking their knowledge and experience with the service. Only 10 completed responses were received of which 7 GPs reported making use of the services. Analysis of these responses will follow.

(ii) Patients' Discharge Forms

A total of 237 discharge forms were analysed. The results are shown table 1.

Table 1 Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
year of birth	221	1915	1992	1952.84	16.848
No. of sessions	230	0	12	6.60	2.608
overall outcome	173	1.0	2.0	1.555	.4984
resulting change in medication	159	0	9	2.95	3.716
Valid N (listwise)	126				

The majority of patients were born between 1935 and 1969, i.e. they were aged between 35 and 70. On average they received 6.6 sessions of acupuncture. The overall outcome was scored 1.0 for "no improvement" and 2.0 for 'much improved' or 'slightly improved'. Approximately half of 173 patients who gave data for this question reported being 'much improved' while the other half were 'slightly improved'.

The most common symptom reported by patients referred to the service was pain, especially back pain, pain in one or more joints, and headaches. A more detailed description of reporting symptoms will follow.

The overall self-rated outcomes differed significantly for the four acupuncturists within the service (tables 2 and 3). Overall improvement was rated as 'much improvement' in 55.5% of 173 cases.

Table 2 Acupuncturist's overall outcome

Count

	overall outcome		Total
acupuncturist	improved	much improved	
acupA	15	35	50
acupB	42	36	78
acupC	10	7	17
acupD	10	18	28
Total	77	96	173

Table 3 Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	9.302(a)	3	.026
Likelihood Ratio	9.449	3	.024
N of Valid Cases	173		

In a similar fashion the reported changes in medication differed significantly across the four acupuncturists (see tables 4 and 5). A change in medication resulting from the acupuncture was reported in 51.6% of 159 cases.

Table 4 Acupuncturist * resulting change in medication Crosstabulation

Count

acupuncturist	resulting change in medication			Total
	no	yes	n/a	
acupA	10	23	16	49
acupB	14	43	18	75
acupC	2	7	8	17
acupD	8	9	1	18
Total	34	82	43	159

Table 5 Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	12.963(a)	6	.044
Likelihood Ratio	13.075	6	.042
N of Valid Cases	159		

3. Cost-effectiveness

It had been hoped to carry out an analysis of cost-effectiveness. Owing to problems with the design of the Discharge Form, it has not been possible to carry out such an analysis. The Discharge Form does not indicate the nature and dosage of medication being taken by the patient prior to and after the treatment. It only asks for an answer to the question: "*Has your medication changed as a result of acupuncture?*" There is also no systematic information kept by the service on the impact of the acupuncture service on the further use of NHS services by patients who have received acupuncture.

4. Discussion

As noted above, problems with the design of the Discharge Form have meant that the data collected were not sufficiently robust to carry out any economic analysis of cost-effectiveness.

The Discharge Form should be re-designed to collect the relevant information. The following design features would improve the usefulness of the form to any future evaluation of cost-effectiveness of the service.

- Make sure that only one symptom is written on each line, the form could include another line to enable a fourth symptom to be noted.
- Present condition as reported by the patient should be noted for each of the symptoms described above.
- The scale should not have 'same' and 'no different' categories as they are too similar. In addition I feel the scale would benefit from a sub scale of the rough time period for any improvement if appropriate.
- The medication change scale could determine if the change is for a prescribed medicine or an over the counter medicine.
    - Also there should be a line for a short description about the nature of the change i.e. quantity of dose before and after course of acupuncture.

These design features are listed below:

Main complaint Symptom 1 _____
Symptom 2 _____
Symptom 3 _____

Present Condition As Reported By Patient:

Symptom 1

Much Improved ☐ Slightly Improved☐ Same☐ Worse☐

How Long Has Any Improvement Lasted:_____

Symptom 2

Much Improved ☐ Slightly Improved☐ Same☐ Worse☐

How Long Has Any Improvement Lasted:_____

Symptom 3

Much Improved ☐ Slightly Improved☐ Same☐ Worse☐

How Long Has Any Improvement Lasted:_____

Symptom 3

Much Improved ☐ Slightly Improved☐ Same☐ Worse☐

How Long Has Any Improvement Lasted:_____

Has your medication changed as a result of acupuncture? Yes☐ No☐

If yes, what is the name of the medication?_____

Details of dosage before acupuncture:_____

Details of dosage after acupuncture:_____

Core Unit 4: Teaching & Training Case Study 1

Setting: [redacted] PCT Department of Public Health

Introduction and Background

The consultant midwife was keen to engage staff in smoking cessation work because smoking cessation in pregnancy is one of their key objectives. The objective was to train the midwives to carry out intensive 1-to-1 support and advice in smoking cessation to pregnant women. The training programme was to be delivered to a group of 50 midwives working in the Borough of [redacted] The group of 50 midwives included 5 who had previously been trained to provide smoking cessation counselling to pregnant mothers and 45 who had not received any previous training in smoking cessation. The 5 who had previously received smoking cessation training were inactive in the field because they did not feel confident, post-training, to provide the relevant services.

Planning and Design of the Training Programme

The training programme was designed to meet the key objective of enabling midwives to provide effective smoking cessation services to their clients, i.e. pregnant women. The programme was structured so that the necessary information, skills and practices were introduced to accommodate trainees with no previous training in psychology. The planning and design of the programme was based on an assessment of training needs as outlined below.

Assessing and Establishing Training Needs

0n April 15th 2004 I met with the consultant midwife to discuss the training needs of the hospital and community midwives. Our discussions focused on the feedback that she had received from the five midwives previously trained in smoking cessation but who had never felt sufficiently confident to provide the service to their clients. The consultant midwife identified two reasons why this previous training had not resulted in smoking cessation services being provided to clients:

The training provided to the five midwives was considered to be too theoretical and not sufficiently practical. The training had provided them with an understanding of

how smoking cessation worked but did not focus on providing the skills, in terms of the practicalities of giving advice and guidance to their clients

The training failed to take account of how the issue of smoking cessation can be raised with clients without damaging the rapport between the midwife and client. The possible detrimental effect on the client rapport was cited as a major concern of the midwives and appeared to be the main reason why the five trained midwives had not attempted to provide smoking cessation services.

The consultant midwife raised an additional personal concern in relation to staff's attitudes towards pregnant smokers. She expressed the view that many of the midwives were sometimes critical and very prescriptive when providing smoking cessation advice to the women. She thought that some of them were judgemental and that this attitude meant that they were unsuccessful when raising the issue of smoking with clients. I reassured her that these issues would be addressed within the training, i.e. the addiction component would create a better understanding of smoking behaviour and the inclusion of the stages of change model (Prochaska and DiClemente (1986)) would give specific guidance as to how to tailor advice appropriately to the needs of the client.

I requested and obtained permission to send the midwives a pre-training questionnaire. This was to gather information to ensure that the training was tailored to meet individual needs and special requirements of the trainees, e.g. arising from disabilities, and to engender a sense of ownership in the training i.e. so that the group would engage more readily in the training.

Our discussions then focused on the structure and content of the training programme. The training would need to encompass all of the core content areas and key learning outcomes identified by the Health Development Agency (HDA) Expert Panel in the Standard for Training in Smoking Cessation Treatment (see practice log Appendices). The learning outcomes were agreed in line with the content of this document and the structure of the programme was provisionally planned. It was decided that the training would be 'experiential', student centred and interactive in order to meet midwives needs for the training to encompass both practical and theoretical aspects. The resources available for training the midwives were then discussed. It was agreed that the midwives would be trained in a small training room adjacent to the antenatal suite and that power-point facilities, flip-chart, pens and tea & coffee would be provided.

The practicalities of carrying out the training were discussed in terms of the timescale involved, i.e. both my prior commitments and the impact of having the midwives off the wards and in training. It was decided that the midwives would have protected learning time and that their work would be covered. However, the Consultant Midwife could only make provision for midwives to have one day to receive smoking cessation training.

The next step was to consider modes of assessment that would be suitable for the training. We explored assessment methods appropriate to the learning outcomes/aims, e.g. for demonstrating knowledge/understanding we discussed the use of case-studies, multiple-choice questions, tests and quizzes and for the performing procedures (i.e. the skills component) we discussed using video recording, an objective structured clinical assessment and mastery assessments. Thus, several methods were discussed in terms of their suitability in respect of midwives' needs, HDA requirements and resources available. Finally, it was decided that the midwives would be assessed informally in a role-play situation where they act as Smoking Cessation Advisors to pregnant women. Communication skills, incorporation of counselling appropriate to the stages of change model (Prochaska and DiClemente (1986)) and adherence to the [redacted] PCT protocol were to be observed and feedback was to be given in order to consolidate their learning. It was agreed that the assessment was to be a general and informal one that would serve to gauge how much of the content trainees were taking in. It was decided that I would carry out the assessment as I have the necessary knowledge to assess performance in relation to the key content areas for smoking cessation, i.e. due to my role as a specialist smoking cessation advisor for pregnant women.

Documentation to denote completion of the course was discussed and it was decided that certification was the most appropriate method and that midwives would receive certificates within two weeks of completion of the training. Finally, key points from the meeting were summarised and it was agreed that I would keep them informed and show them my training plan for comment before finalising the training programme. Contact details were exchanged and the meeting ended.

Planning the Training

A training Plan was then developed based on the identified training needs of the hospital and community midwives. Additional content material relating to the National

Institute of Clinical Excellence Guidance on Nicotine Replacement Therapy in Pregnancy was also incorporated into the plan as I consider training in this aspect of counselling to be crucial. The midwives need this essential information to adequately inform pregnant mothers about the risks associated with NRT in pregnancy. It is essential for pregnant women to carry out a fully informed risk benefit analysis prior to smoking cessation treatment (See Appendix A)

After deciding upon the content of the training. I looked at the main themes arising in the literature around learning and education, i.e. those of the Behaviourist (Skinner, Pavlov), Cognitive (Piaget, Gagne), Social (Bandura) and Humanist (Mazlow, Rogers) orientations. There was some overlap and some contrasting ideas regarding the process of learning and education and the role that educators take and to some extent the different theories drew upon each other. I decided to focus Kolb's 1984 model (see practice log appendices) because it incorporates the learning process, learning styles of the audience and experiential learning. Kolb's model is in line with theories specific for adult learning such as Knowles 1974 theory of andragogy, which emphasises that adult learning is a process leading to the production of knowledge, i.e. it's a re-conceptualisation of knowledge and that the focus should be more on process and less on the content being taught; it is a model that makes the following assumptions about the design of learning:

- Adults need to know why they need to learn something
- Adults need to learn experientially
- Adults approach learning as problem solving, and,
- Adults learn best when the topic is of immediate value.

Thus strategies i.e. case studies, role playing and self –evaluation were incorporated in the training plan and I adopted the role of facilitator or resource rather than the didactic lecture model.

Training Methods

I considered it to be essential to ensure that a variety of training methods were incorporated in order to maximise learning opportunities for the trainees. The learning styles models that I examined, i.e. Kolb, the Visual-Auditory-Kinaesthetic (VAK) and Herrmann's 'whole brain' model (see practice log appendices), advocate that

individuals have preferred, or in some cases, a mixed or evenly balanced blend of learning styles based on factors such as their brain type and dominance; however, all of these models posit that individuals are capable of learning under any style or intelligence, no matter what the preference is, and that using a variety of learning styles is advantageous to the learner. Consequently, I concluded that the training would need to utilise learning activities appropriate to segments of the learning style models and the most appropriate media to deliver each particular section i.e. the one that I considered to be most helpful in getting participants to understand and retain the information. Advanced plans of the training session were given to the consultant midwife for comment and adjustment before finalising the training programme.

Delivered training programmes encompassing psychological knowledge, skills and practices. Training was delivered on April 23rd 2004. It was necessary to arrive half an hour before the training session started in order to ensure that the necessary resources and materials were available to conduct the training session, i.e. flip chart, pens, power point facilities and refreshments. Tables and chairs were arranged to maximise trainee comfort during the training, e.g unimpeded view of the flipchart, power-point presentation and trainer. Furthermore, the furniture was arranged to facilitate trainee-trainer and trainee-trainee interaction (including my ability to monitor trainees progress with the minimum of movement around the room). Training packs with handouts were placed on each participant's chair. I ensured that the temperature of the room was comfortable and conducive to active learning and set up the laptop and data projector in preparation to conduct the session.

Trainees were welcomed warmly and invited to obtain refreshments. Once participants had arrived, I introduced myself and introductions were made in terms of participants' names and what they wanted to obtain from the course.

The training was delivered using the planned methods relevant to the learning requirements of the group, the agreed aims, objectives & outcomes of the programme and the specified models of teaching/learning (see Appendix A).

Trainees were supported throughout the learning programme. They were encouraged, given appropriate feedback and questions, problems, queries and issues were responded to effectively as they arose; in addition to this I ensured that I was available during breaks for discussion.

During the training, materials and implementation methods were adapted as necessary. For example, time became more limited due to an extended coffee break (there was very productive exchanges in the coffee break) and it became necessary to adapt the training session, i.e. make the next session shorter without undermining the quality of the programme so that learning would not be compromised.

Informal assessment was carried out both during role-play and in the question/answer sessions which made apparent any gaps in knowledge which were subsequently addressed. Evaluation forms were given out at the end of the training programme to ensure that participants had an avenue to feedback their views on the training session and to indicate whether the training was meeting their needs. Further additional informal evaluations were sought after the session via informal discussion with trainees, with the Consultant Midwife and with the Personal Development Midwife; these focused on, inadequacies and how they might be rectified, especially with regards to training delivery. Feedback was positive and constructive.

In practice I continually monitor the success rates of the advisors (I meet with the smoking cessation co-ordinator and smoking cessation administrator who has access to the data-base) I am available as a specialist resource for the trainees post training and provide supervision and follow-up to trainees who need extra support. We review and continually monitor our service in relation to throughput and service quality i.e. the number of quits and support new advisors who need extra support. We receive documentation on national figures and meet with other smoking cessation co-ordinators who are doing well to discuss best practice. Furthermore, I keep my reading up-to-date in order to make sure that the knowledge that I am imparting is up to date and to ensure that I am delivering the best service I can to the trainees.

Reflection

I began the reflection process by examining the evaluation forms (Appendix C); the responses to questions and the comments of the participants were very positive (Appendix D & evaluation sheets in practice log appendices), i.e. all participants enjoyed the training, showed great enthusiasm and worked well together in groups. Participants found the training to be beneficial and felt well equipped to support pregnant women with smoking cessation (see evaluation sheets in practice log Appendices). One participant felt that there was too much information to take in for one day's training; this was a valid point because there was a lot of additional information

for this group of trainees, regarding the health impact of smoking on the physiology of mother and baby. I considered the benefits of sending participants more reading materials prior to training so as not to overburden them with information and felt this was a remedy. Nevertheless, the identified learning outcomes were met, i.e. I noticed a shift in midwives' attitudes towards pregnant women smoking, most notably they appeared much less judgemental after learning about the physiology and psychology of addiction.

All participants fared well in the informal assessment and had managed to maintain a rapport with the pregnant mother during the role-play scenario. Thus the teaching and learning materials were effective, learning was consolidated and my aims and objectives for the training session were achieved. However, the training session t go exactly as planned from my point of view; the training room was adjacent to the antenatal suite and sometimes the training was disrupted by the high pitched distressing screams of women in labour! There were times during the training when everyone went quiet listening to the screams, then raucous laughter erupted and comments about the mother ensued; the midwives commented that they were accustomed to this 'noise' but personally, I found it both disruptive and distressing. From my point of view, it interfered with the smooth running of the programme as I felt the noise affected the atmosphere of the training session and broke the participants' concentration. The experience encouraged me to examine the effectiveness of my facilitation skills as I noted how I found it difficult to get participants re-engaged following the incident, i.e. I found that it was difficult for me to make myself heard above the noise and get them to concentrate again. While I had felt that I had kept control during previous training sessions in this context I realised my communication skills were lacking in respect of commanding attention in this session, because of the excessive noise. I decided to get lessons from a voice coach to help my confidence in future training sessions and in the meantime, consider acquiring a bell or a similar device as I have seen trainers use bells in training sessions with some success. On a more positive note I felt that I dealt with the situation calmly and the participants seemed unaware of my anxiety and unease, i.e. these feelings did not impact on the training session.

In future sessions I would take a closer look at venues when planning the training as I had not considered the noise factor of an antenatal suite; a different venue was a top priority for the next session. I discussed this issues with the Consultant midwife when I met with her for a debriefing of the training session. She told me that

she had had very positive feedback from the midwives when I raised the issue of a possible change of venue for subsequent sessions, she explained that in view of its' accessibility it was the preferred venue, I accepted this argument and I resolved to improve my skills in dealing with noise intrusions

Planning and delivering this training session has improved my skills, abilities and awareness of professional development needs in the following key areas:

I feel better equipped to put aside my personal feelings, become more flexible and train with less than ideal resources;

I need to work on commanding attention through voice work and have other means of controlling groups at my disposal, e.g. a bell;

I could improve my effectiveness as a trainer by distributing reading materials prior to training, particularly with groups that have more subject matter than usual to cover.

I have learnt a lot from this training experience and will integrate this knowledge to improve subsequent training sessions.

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Core Unit 4: Teaching & Training Case Study 2

Introduction and Background

The Public Health Programmes Manager, the [redacted] PCT Head of Pharmacy, the [redacted] PCT Prescribing Advisor and myself met to discuss training the community pharmacists in smoking cessation work. Including the pharmacists in the delivery of smoking cessation interventions within the community would serve to increase accessibility of these services to [redacted] residents i.e. because pharmacies are open late evenings and weekends. The Head of Pharmacy and the Prescribing Advisor were keen to engage staff in this work because smoking cessation was one of the key objectives in the new pharmacy contract. The objective was to train community pharmacists to carry out intensive 1-to-1 support and advice in smoking cessation to [redacted] residents. The training programme was to be delivered to a group of pharmacists working in the Borough of [redacted].

Planning and Design of the Training Programme

The training programme was designed to meet the key objective of enabling community pharmacists to provide effective smoking cessation services to their clients. The programme was planned so that the necessary information, skills and practices were introduced to accommodate trainees with no previous training in psychology. The planning and design of the programme was based on an assessment of training needs as outlined below.

Assessing and Establishing Training Needs.

On June 3rd 2004 I met with the [redacted] PCT Head of Pharmacy, the [redacted] PCT Prescribing Advisor and the Public Health Programmes Manager to discuss the training needs of the community pharmacists in [redacted]. The training needs of the pharmacists were discussed in detail as the training had to be needs-led in addition to encompassing all of the core content areas and key learning outcomes identified in the Health Development Agency (HDA) Expert Panel in the Standard for Training In Smoking Cessation Treatment (see appendices in practice log).

The Head of Pharmacy relayed that it was essential that the training programme incorporated counselling skills - the pharmacists needed help with this aspect because they were not used to it in the day to day work of selling and advising on drugs. I

advised him that these issues would be addressed within the training, i.e. some counselling skills would be included in the training and the inclusion of the stages of change model (Prochaska and DiClemente (1986)) would give specific guidance as to how to tailor advice appropriately to the needs of the client.

In order to adequately tailor the programme to the trainees' needs, it was agreed that I should send out pre-training questionnaires to pharmacists interested in providing stop smoking counselling prior to training. This was to gather information to ensure that the programme would meet individual needs and special requirements of the trainees, e.g. arising from disabilities, and to engender a sense of ownership in the training i.e. so that the group would engage more readily in the training.

The learning outcomes were agreed in line with the HDA and the structure of the programme was provisionally planned. It was decided that the training would be 'experiential' as pharmacists needed to practice the counselling skills fundamental for eliciting behaviour change.

It was then necessary to discuss resources available for training the pharmacists. It was decided that the venue and all other resources had to be found and funded by the PCT (i.e. power-point facilities, flip-chart, pens and tea & coffee etc.) and that locum cover had to be paid for if the pharmacists were to be engaged in smoking cessation training. It was decided that the pharmacists would find the locum cover and invoice the PCT. We devised a structured payment plan for pharmacists carrying out smoking cessation work; Pharmacists would receive payment of £7 per session of smoking cessation work and would receive no more than £35 as clients were to be seen for 5 sessions maximum, in line with the PCT protocol. They would receive payment for NRT issued at cost price plus VAT. This was in line with payments offered by other smoking cessation services nationally. I was to devise a service level agreement contract and show it to the PCT head pharmacist before it was sent out to those interested in signing up to carry out smoking cessation work as a part of the extended smoking cessation team.

The practicalities of carrying out the training were then discussed in terms of the timescale involved, i.e. both my prior commitments and the issues of finding a suitable venue and giving the pharmacists enough time to find locum cover. The smoking cessation training was to be condensed into a one-day training programme due to the practicalities of having the pharmacists away from their pharmacies and the expense of

finding locum cover for two days. Dates for the training were to be forwarded to the Head of Pharmacy for distribution at the Pharmacy Forum Meeting.

The next step was to consider modes of assessment that would be suitable for the training. We explored assessment methods appropriate to the learning outcomes/aims, e.g. for demonstrating knowledge/understanding we discussed the use of case-studies, multiple-choice questions, tests and quizzes; for the performing procedures (i.e. the skills component) we discussed using video recording, an objective structured clinical assessment, and mastery assessments. Thus, several methods were discussed in terms of their suitability in respect of pharmacists' needs, HDA requirements and resources available. Finally, it was decided that the pharmacists would be assessed informally in a role-play situation where they act as Smoking Cessation Advisors to clients. Communication skills, incorporation of counselling appropriate to the stages of change model (Prochaska and DiClemente (1986)) and adherence to the [redacted] protocol were to be observed and feedback was to be given in order to consolidate their learning. It was agreed that the assessment was to be a general and informal one that would serve to gauge how much of the content trainees were taking in. It was decided that the PCT's Prescribing Advisor would be present throughout the training and that I would carry out the assessment: I have the necessary knowledge to assess performance in relation to the key content areas for smoking cessation due to my work experience as a specialist smoking cessation advisor. Documentation to denote completion of the course was discussed and it was decided that certification was the most appropriate method and that pharmacists would receive certificates within two weeks of completion of the training. Finally, key points from the meeting were summarised and it was agreed that I would keep them informed and show them my training plan for comment before finalising the training programme. Contact details were exchanged, and the meeting ended.

Planning the Training

The content of the training programme was then formally devised. It was important to make sure that the condensed version of the smoking cessation training still incorporated all of the key skills and competencies stipulated by the HDA and to ensure that the quality of the programme was preserved. All components discussed in the pre-training meeting were incorporated into a training plan (see appendix B). In addition, I incorporated supplementary material, i.e. additional discussion and handouts on Nicotine Replacement Therapy (NRT) and drug interactions, contra-indications and cautions in NRT use in particular clients and screening clients for use of Buproprion (Zyban). I thought that this was particularly important for pharmacists because unlike midwives, they actually give the clients NRT and they need to be aware of this information, in order to cover themselves professionally.

After deciding upon the content of the training. I looked at the main themes arising in the literature around learning and education, i.e. those of the Behaviourist (Skinner, Pavlov), Cognitive (Piaget, Gagne), Social (Bandura), and Humanist (Mazlow, Rogers) orientations. There was some overlap and some contrasting ideas regarding the process of learning and education and the role that educators take and to some extent the different theories drew upon each other. I decided to focus Kolb's 1984 Experiential model (see practice log appendices) because it incorporates the learning process, learning styles of the audience and experiential learning. Kolb's model is in line with theories specific for adult learning such as Knowles 1974 theory of andragogy, which emphasises that adult learning is a process leading to the production of knowledge, i.e. it's a re-conceptualisation of knowledge and that the focus should be more on process and less on the content being taught. It's a model that makes the following assumptions about the design of learning:

- Adults need to know why they need to learn something
- Adults need to learn experientially
- Adults approach learning as problem solving, and
- Adults learn best when the topic is of immediate value

Thus strategies i.e. case studies, role playing and self –evaluation were incorporated in the training plan and I adopted the role of facilitator or resource rather than the didactic lecture model.

Training Methods

The learning styles models that I examined, i.e. Kolb, the Visual-Auditory-Kinaesthetic (VAK) and Herrmann's 'whole brain' model (see practice log appendices), advocate that individuals have preferred, or in some cases, a mixed or evenly balanced blend of learning styles based on factors such as their brain type and dominance; however, all of these models posit that individuals are capable of learning under any style or intelligence, no matter what the preference is, and that using a variety of learning styles is advantageous to the learner. Consequently, I concluded that the training would need to utilise learning activities appropriate to segments of the learning style models and the most appropriate media to deliver each particular section i.e. the one that I considered to be most helpful in getting participants to understand and retain the information. In view of this I considered it was essential to ensure that a variety of training methods were incorporated in order to maximise learning opportunities for the trainees. For example, in the pharmacists' training, a video example of a smoking cessation counselling session was incorporated into the programme to enhance their understanding of what a counselling session might look like, as it was thought that unlike nurses, counselling hadn't been included in their formal training. Advanced plans of the training session were given to the consultant midwife for comment and adjustment before finalising the training programme.

Delivered training programmes encompassing psychological knowledge, skills and practices. The training was delivered on June 18th 2004. The pre-training routine was similar to that discussed above in the section on training the midwives, i.e. the arrival and setting up procedure, and the training was delivered using the planned methods relevant to the learning requirements of the group, the agreed aims, objectives and outcomes of the programme and the specified models of teaching/learning (appendix B). Again, students were supported throughout the learning programme. They were encouraged, given feedback and questions, problems, queries and issues were responded to effectively as they arose (see evaluations in practice log). Once more, I ensured that I was available during breaks for discussion. Materials and implementation methods were adapted as necessary. For example, I went into more depth on a topic if that was requested by a participant.

Informal assessment was carried out both during role play and the question/answer sessions. Any gaps in knowledge were then identified and were subsequently addressed. Evaluation forms were given out at the end of the training

programme to ensure that participants had an avenue to feed-back their views on the training session and indicate whether the training that they had received, succeeded in meeting their needs (see practice log appendices). I met with the PCT's Head of Pharmacy and the prescribing adviser for a debriefing of the training session and they said that they had received positive feedback at the pharmacy forum. Certificates were posted out to participants a couple of days post-training, the service level agreements sent out and the database updated

I continually monitor the success rates of the advisors (I met with the smoking cessation co-ordinator and smoking cessation administrator who has access to the data-base) and I am available as a specialist resource for the trainees post training and provide supervision and follow-up to trainees who need extra support. We review and continually monitor our service in relation to throughput and service quality i.e. the number of quits and support new advisors who need extra support. We receive documentation on national figures and meet with other smoking cessation co-ordinators who are doing well to discuss best practice. Further, I keep my reading up-to-date in order to make sure that the knowledge that I am imparting is up to date and to make sure that I am delivering the best to the trainees

Reflection

I began the reflection process by reading the evaluation forms and I felt that the training session had gone well, i.e. it had gone according to plan and the feedback and evaluation was very encouraging (Appendix E). Participants were attentive and enthusiastic and worked well together in groups and facilitation of the training went smoothly. Participants were very positive about the training session and found the training to be of value and felt well-equipped to take on the role of Smoking Cessation Advisor (see evaluation sheets in practice log Appendices). The identified learning outcomes were met as evidenced by the participants all faring well in the informal assessment. Thus the teaching and learning materials were effective, learning was consolidated and the aims and objectives for the training session were met. However, I noticed that a few participants seemed disgruntled at having to participate in role play and they had problems getting into the spirit of it. This was perhaps partly due to their being unused to counselling in their day-to–day work in their pharmacies e.g I recognised that it can be difficult to project oneself into an imaginary situation that you have no prior experience of. This may have made them uncomfortable or nervous at the

prospect of this exercise. Undertaking the role play was one of the objectives of the session but perhaps I could have done more to take the fear out of the exercise by being clearer about why I wanted them to do a role play and what I wanted them to gain from the experience. For example, I sometimes use a theatre analogy to explain the relevance of the role play: I might say ‘actors spend hours rehearsing a twenty-minute scene. They do it again and again to get it right; to get the behaviours and the relationships right, to make sense of the scene and to understand the issues. They get feedback in the form of notes from the director, which they will immediately apply to the work in hand. They carry on in this way until it's perfect and the scene becomes part of them’. However, I neglected to share the analogy with the group on this occasion and this information might have served to make participants less wary of the role play and made them more open to the exercise. I use role play to both assess and develop trainees’ learning.

I underplayed the assessment part due to its being informal but maybe it would have been more helpful to participants if I had been clearer about the competency level expected of them and given them specific measurable outcomes to put their minds at ease. I could have also emphasised that they were not expected to give a 'performance' - reassuring them in that way would have probably helped diffuse fear and tension. Further, I did not put them through the role play experience until the end when I was sure that they had the necessary knowledge for the role play scenario. However, maybe leaving it until last caused, 'the dreaded role play' to loom large in their minds. Next time it might be more beneficial to introduce people to the role play experience gently by holding mini role plays earlier and staging them throughout the session. This might de-mystify the experience for the pharmacists unused to a counselling scenario and it might make them more comfortable with the idea of 'performing' in public.

In summary, I have learnt the importance of being consistent across training sessions – for example, using the theatre analogy would have been helpful with the pharmacist trainees. I also need to do more to allay trainees’ fears and concerns during training - in this case by providing clarity on why role play was needed and the competency level expected, and by conducting mini-role plays throughout the session. I have learnt a lot from this particular experience and will integrate this knowledge to improve subsequent training sessions.

Training Session 3 (Recorded on video)

Reflections on videoed training session

The training of a mixed group of 14 health care and community staff took place on the 12th and 13th December in Kings Church[redacted]. The video was taken on the second day of the training. The second day was mainly practical activity as the first days training is very theoretical, so the video shows me interacting with the trainees and demonstrating via video a smoking cessation intervention before trainees performed the role play. Participants were very positive about the training session and found the training to be of value and felt well-equipped to take on the role of smoking cessation advisor (see evaluation sheets in practice log appendices). I felt that facilitation of the training went smoothly and according to plan. I considered that I interacted well with the trainees and developed a strong rapport. The trainees were attentive and seemed to enjoy the training. Facilitation of the group sessions was particularly easy as the group seemed to gel well together. This may have been due to the fact that the trainees were of various professions and therefore had different ideas and insights. Participants both developed and applied the necessary knowledge and skills by the end of the training session. Thus, teaching and learning materials were adequate, appropriate and effective. The learning outcomes were met, trainees all fared well in the informal assessment- therefore, the aims and objectives for the training session were met, which is evident from the observation report (appendix F). However, one failing was a concluding statement summarising the key point to be taken away by the trainees. The participant said that striking an inspirational note would have been a good way to end the session. I reflected on this point and agreed that the participant had a valid point – ending in an inspirational fashion would have improved the training session. I was conducting the training so as to ensure that upon completion of the programme, trainees would be well-equipped to carry out the role of smoking cessation counsellor but I now realised that I had not given enough consideration to finding ways to inspire the trainees. This was an important aspect of training that I had overlooked as the aim of the training was to produce well-trained, effective smoking cessation advisors and inspiring trainees could only have a positive effect on their performance as smoking cessation counsellors. Initially, I decided that a good way for me to start looking for methods to inspire my trainees would be to see what training opportunities were available to me as a trainer. I discovered a workshop conducted by [redacted], 'Training for Trainers' and felt that this might among other things, provide me with ideas as how to inspire trainees.

However, the course was fully booked until the end of the year so I was unable to attend. I considered my alternative to be to shadow [redacted], Research Psychologist at the Tobacco Research Unit, [redacted] Clinical Psychologist at the [redacted] NHS smoking cessation clinic as she is very passionate about smoking cessation and is known to be a good speaker who can inspire people in the smoking cessation field.

[redacted]'s training was certainly passionate and inspiring and she related her own story to the trainees, which explained why, on a personal level, it was important to her to work in the smoking cessation field. I concluded that the passion and confidence that were clear to see in her training were a result of her intense personal motivation combined with a deep knowledge of the subject matter and her many years of experience in this field: as well as her moving personal story, she was able to highlight the most cynical and objectionable tactics employed by the tobacco companies and explain in detail and in stark terms, how nicotine impacts the physiology of the brain. She does all of this concisely and coherently and in the process, she completely engages and motivates everyone in the room. This is what I would understand as inspiring the trainees.

Having been very impressed by [redacted]'s example, I decided that the key thing that I could take from her approach was to endeavour to incorporate more personal experiences and stories into my training sessions and to monitor which ones are best received by trainees. In this way I would hope to gradually build up a reliable store of material with which I could feel confident that I could inspire trainees to feel truly motivated in the role of smoking cessation advisor.

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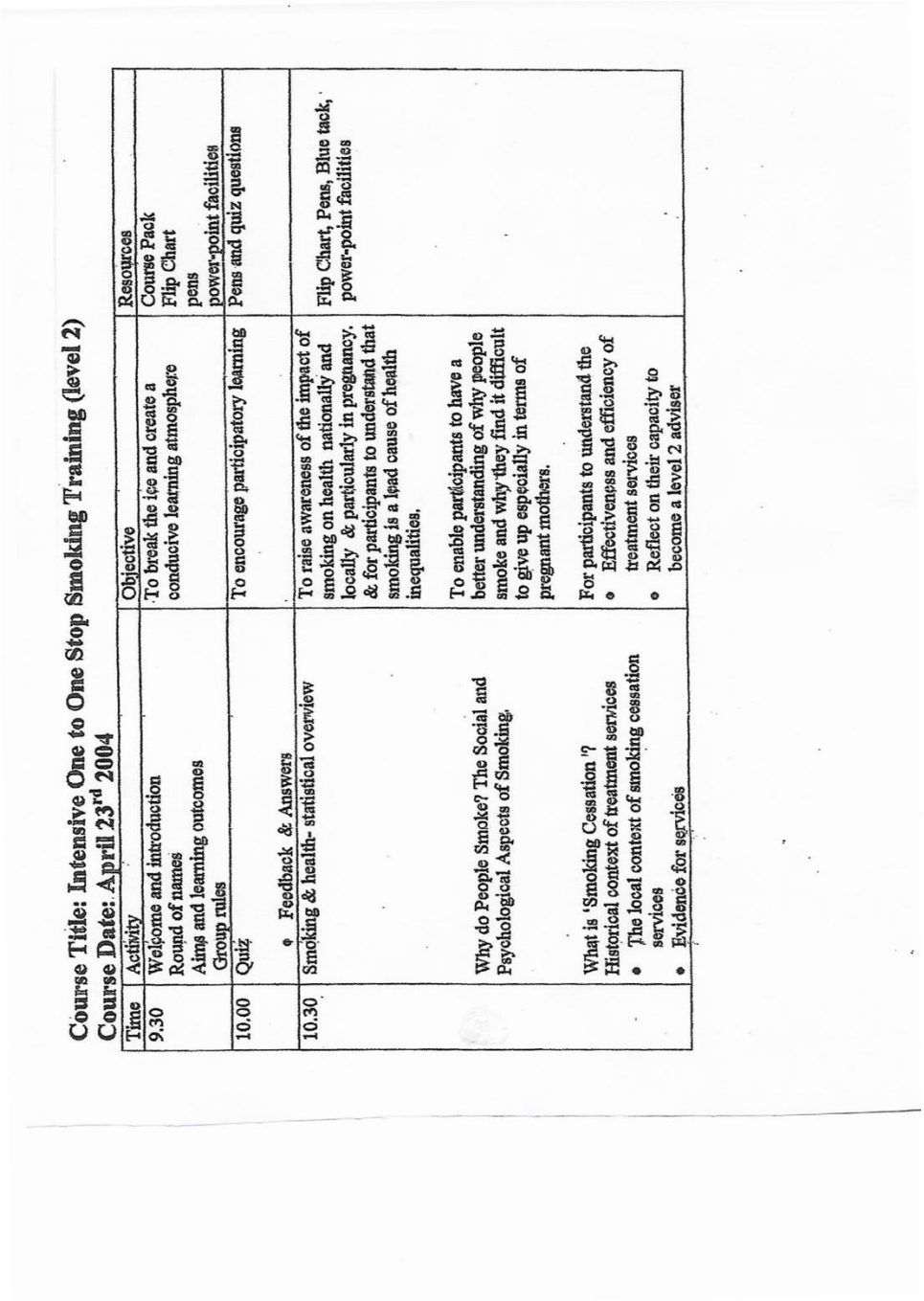
Appendices for Teaching and Training

Appendix A (page 1 of 4)

Training Planner



Course Title: Intensive One to One Stop Smoking Training (level 2)
Course Date: April 23rd 2004

Time	Activity	Objective	Resources
9.30	Welcome and introduction Round of names Aims and learning outcomes Group rules	To break the ice and create a conducive learning atmosphere	Course Pack Flip Chart pens power-point facilities
10.00	Quiz • Feedback & Answers	To encourage participatory learning	Pens and quiz questions
10.30	Smoking & health- statistical overview Why do People Smoke? The Social and Psychological Aspects of Smoking. What is 'Smoking Cessation '? Historical context of treatment services • The local context of smoking cessation services • Evidence for services	To raise awareness of the impact of smoking on health nationally and locally & particularly in pregnancy. & for participants to understand that smoking is a lead cause of health inequalities. To enable participants to have a better understanding of why people smoke and why they find it difficult to give up especially in terms of pregnant mothers. For participants to understand the • Effectiveness and efficiency of treatment services • Reflect on their capacity to become a level 2 adviser	Flip Chart, Pens, Blue tack, power-point facilities

	• The role of the level 2 Adviser • Structures required for practice	• Understand what it means to provide intensive one to one support to smokers • Be aware of the local services available for smokers	
11.00	Components of a cigarette & their action on the body. Each body system will be explored. especially the effects of smoking in pregnancy	To increase participants understanding of the chemical compounds of inhaled tobacco and how they affect the body, particularly in pregnancy	power-point facilities flip-chart & pens
11.30	**BREAK**		
11.45	Nicotine Addiction & Withdrawal	To describe in non-technical terms the pharmacological effects of nicotine and the mechanisms of addiction. To increase knowledge of withdrawal symptoms in order to be able to advise and support clients , both with use of pharmacotherapy and behavioural methods. To provide information on NRT use in pregnancy & lactation.	Flip Chart, Pens, Blue tack, power-point facilities Nicotine Replacement Therapy Products.

13.00	LUNCH		
13.45	Raising the issue	For participants to introduce the topic of smoking in a sensitive supportive & supportive way. For participants to understand the importance of regularly raising the issue of smoking with pregnant and post-partum women	Group exercises Flip Chart, Pens, Blue tack,
14.15	The process of Change in the Antenatal and Post-natal Phase	To illustrate the process of change for this group of women To explore how participants can support women throughout the change process To increase participants' confidence in their ability to work with a client to assess their readiness to quit. quit	Flip Chart, Pens, Blue tack, Group exercises
14.45	Initial Assessment - Stage 1 of treating smokers	To teach participants how to assess nicotine dependence and engage with and support smokers.	powerpoint facilities Role Play
15.15	Quit Date - stage 2 to 5 of treating smokers	To provide participants with the necessary tools needed to support and maintain a quit attempts.	powerpoint facilities role play

15.30	Carbon Monoxide Monitoring	For participants to be aware of how to use this piece of equipment and understand the meaning of the results.	CO monitors Handouts
15.50	Record Keeping -monitoring Form -Service Level Agreement	For participants to understand the structures and processes of the Stop Smoking Service	
16.20	Questions & Evaluation		

Appendix B (page 1 of 4)

Training Planner

Training Planner

Course Title: Intensive One to One Stop Smoking Training (level 2)
Course Date:18th June 2004

Time	Activity	Objective	Resources
9.30	Welcome and introduction Round of names Aims and learning outcomes Group rules	To break the ice and create a conducive learning atmosphere	Course Pack Flip Chart pens power-point facilities
10.00	Quiz • Feedback & Answers	To encourage participatory learning	Pens and quiz questions
10.30	Smoking & health- statistical overview Why do People Smoke? The Social and Psychological Aspects of Smoking. What is 'Smoking Cessation '? Historical context of treatment services • The local context of smoking cessation services • Evidence for services	To raise awareness of the impact of smoking on health nationally and locally & for participants to understand that smoking is a lead cause of health inequalities. To enable participants to have a better understanding of why people smoke and why they find it difficult to give up For participants to understand the • Effectiveness and efficiency of treatment services • Reflect on their capacity to become a level 2 adviser	Flip Chart, Pens, Blue tack, power-point facilities

	• The role of the level 2 Adviser • Structures required for practice	• Understand what it means to provide intensive one to one support to smokers • Be aware of the local services available for smokers	
11.00	Components of a cigarette & their action on the body. Each body system will be explored.	To increase participants understanding of the chemical compounds of inhaled tobacco and how they affect the body,	power-point facilities flip-chart & pens
11.30	BREAK		
11.45	Nicotine Addiction & Withdrawal	To describe in non-technical terms the pharmacological effects of nicotine and the mechanisms of addiction. To increase knowledge of withdrawal symptoms in order to be able to advise and support clients , both with use of pharmacotherapy and behavioural methods. To provide information on NRT/Zyban use including common cautions & contraindications, Zyban Screening, drug interactions & quitting smoking & prescribed medications.	Flip Chart, Pens, Blue tack, power-point facilities Nicotine Replacement Therapy Products.

13.00	LUNCH		
13.45	Raising the issue	For participants to raise the issue of smoking in an effective way.	Group exercises Flip Chart, Pens, Blue tack, video
14.15	A Model of Behaviour Change -Stages of Change	To enable participants to understand the 'stages of change' model and its application to smokers To explore how participants can support smokers throughout the change process To increase participants' confidence in their ability to work with a client to assess their readiness to quit. quit	Flip Chart, Pens, Blue tack, Group exercises
14.45	Initial Assessment - Stage 1 of treating smokers	To teach participants how to assess nicotine dependence and engage with and support smokers.	powerpoint facilities Role Play
15.15	Quit Date	To provide participants with the	powerpoint facilities

	- stage 2 to 5 of treating smokers	necessary tools needed to support and maintain a quit attempts.	role play
15.30	Carbon Monoxide Monitoring	For participants to be aware of how to use this piece of equipment and understand the meaning of the results.	CO monitors Handouts
15.50	Record Keeping -monitoring Form -Service Level Agreement	For participants to understand the structures and processes of the Stop Smoking Service	
16.20	Questions & Evaluation		

Appendix C

EVALUATION FORM

LEVEL 1
SMOKING CESSATION INTERMEDIATE LEVEL TRAINING

EVALUATION

Thank you for attending the Level 1 Smoking Cessation Intermediate Level Training. This evaluation form is designed to find out how you feel about the programme that you have just completed.

Please give this programme an overall rating in each of the following areas by circling the most appropriate response.

1. Was the information peovided in an interesting and stimulating way?

   Excellent **Good** **Average** **Poor**

2. Following this course do you have a better understanding of what it means to provide a one-to-one support to smokers?

   Yes **No**

3. Was the training provided in a professional manner?

   Excellent **Good** **Average** **Poor**

4. Were all your questions answered satisfactorily?

   Excellent **Good** **Average** **Poor**

5. Would you recommend this training to your colleagues?

   Yes **No**

6. Did you feel the venue was satisfactory for the nature of the course?

   Yes **No**

We value feedback from people attending our training programme. Any comments that would help us improve the programme in the future would be much appreciated.

Comments

.....

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Thank You.

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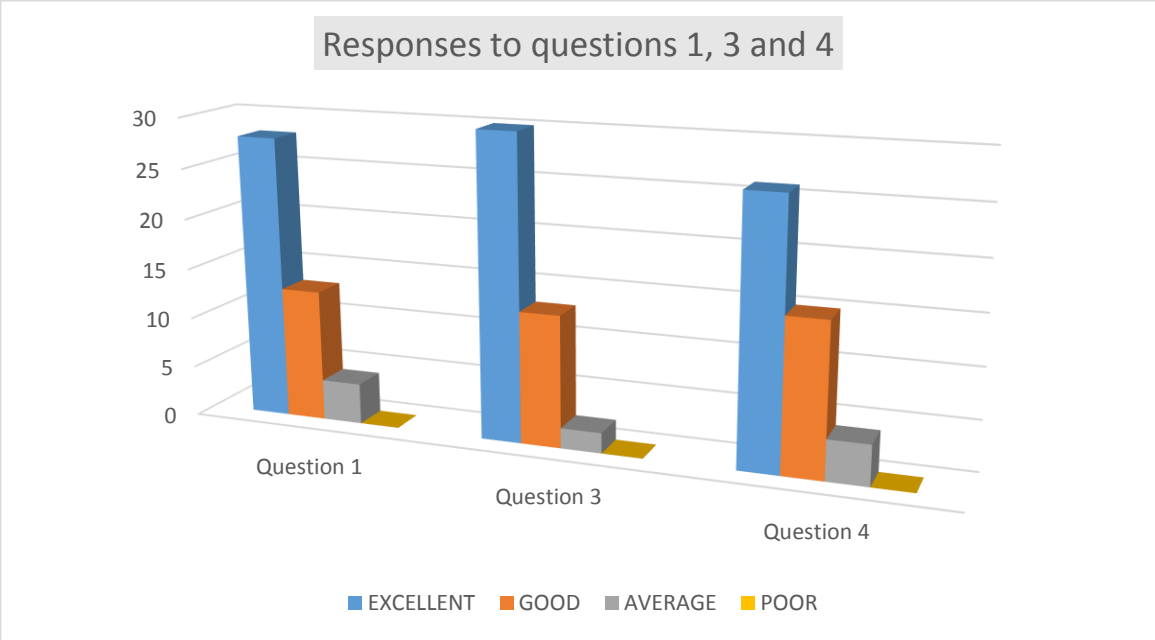
Appendix D (page 1 of 2)

ANALYSIS OF EVALUATION FEEDBACK FORMS (MID WIVES)

Level 2 Smoking Cessation Intermediate Level Training.

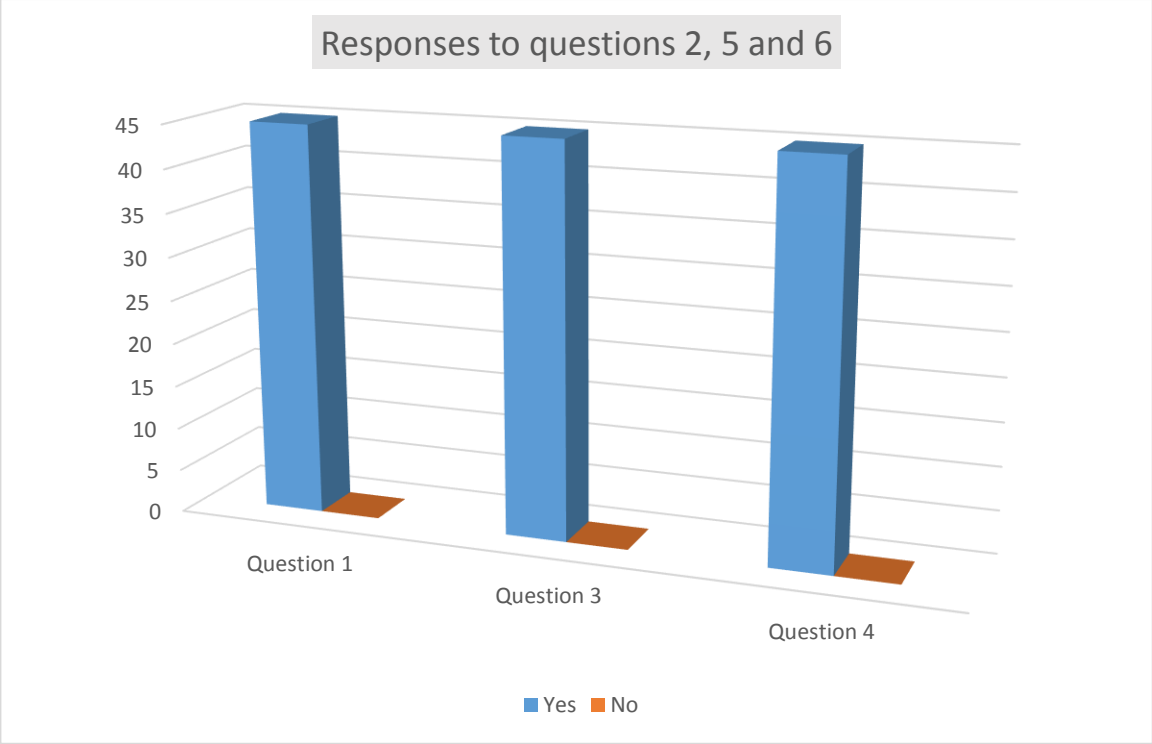


Key:

Question 1: was the information provided in an interesting and stimulating way?

Question 3: was the training provided in a professional manner?

Question 4: where are all your questions answered satisfactorily?



Key:

Question 2: following this course do you have a better understanding of what it means to provide intensive one-to-one support to smokers?

Question 5: would you recommend this training to your colleagues?

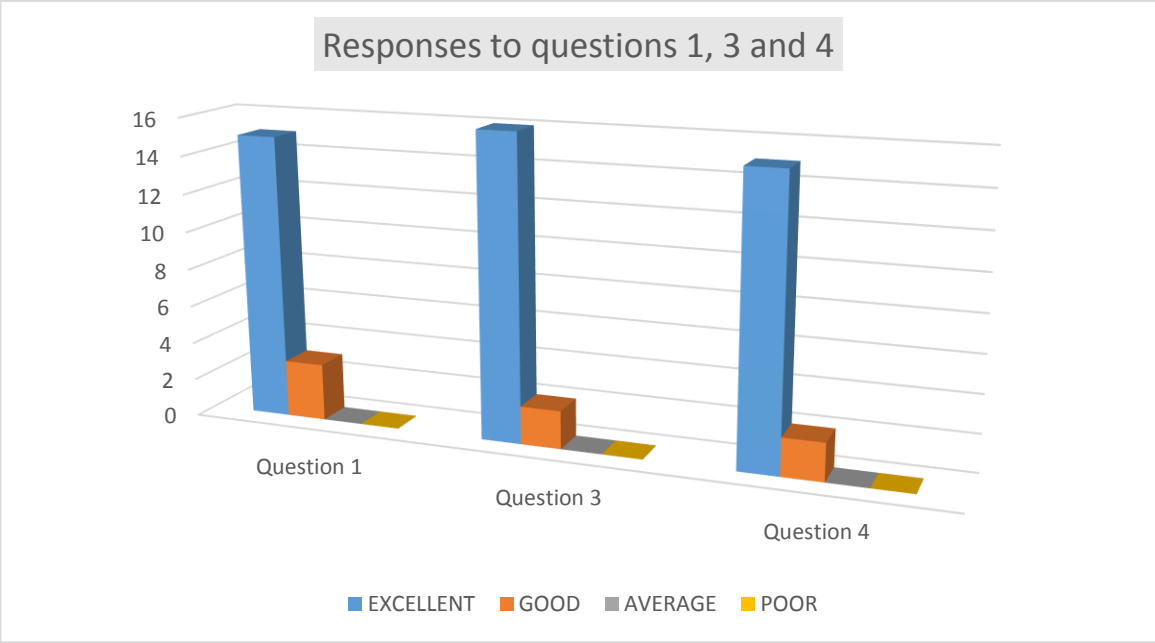
Question 6: do you feel the venue was satisfactory for the nature of this course?

Trainee's comments:

- Very informative program very professionally delivered.
- I thought this was pitched at just the right level.
- This is exactly what I needed - I feel much better about dealing with patients now
- This training had a lot of useful information which I'm going to be using a lot, so thank you for that.
- I'd definitely recommend this to anybody who wanted to learn about smoking cessation, it was excellently handled. Thanks.
- What I liked about this training is that it was focused on being practical but the theory was explained as well.
- I thought the answers to the questions was very good.

ANALYSIS OF EVALUATION FEEDBACK FORMS (PHARMACISTS)
Level 2 Smoking Cessation Intermediate Level Training. (JUNE 2004)

Feedback Forms.

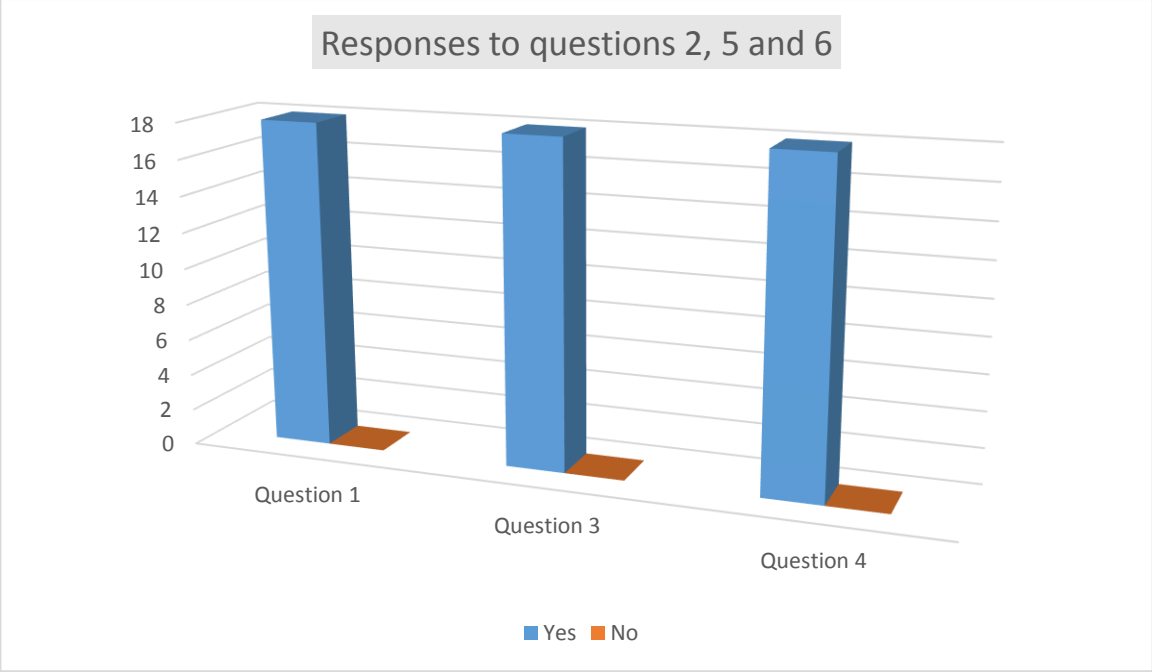


Key:

Question 1: was the information provided in an interesting and stimulating way?

Question 3: was the training provided in a professional manner?

Question 4: where are all your questions answered satisfactorily?

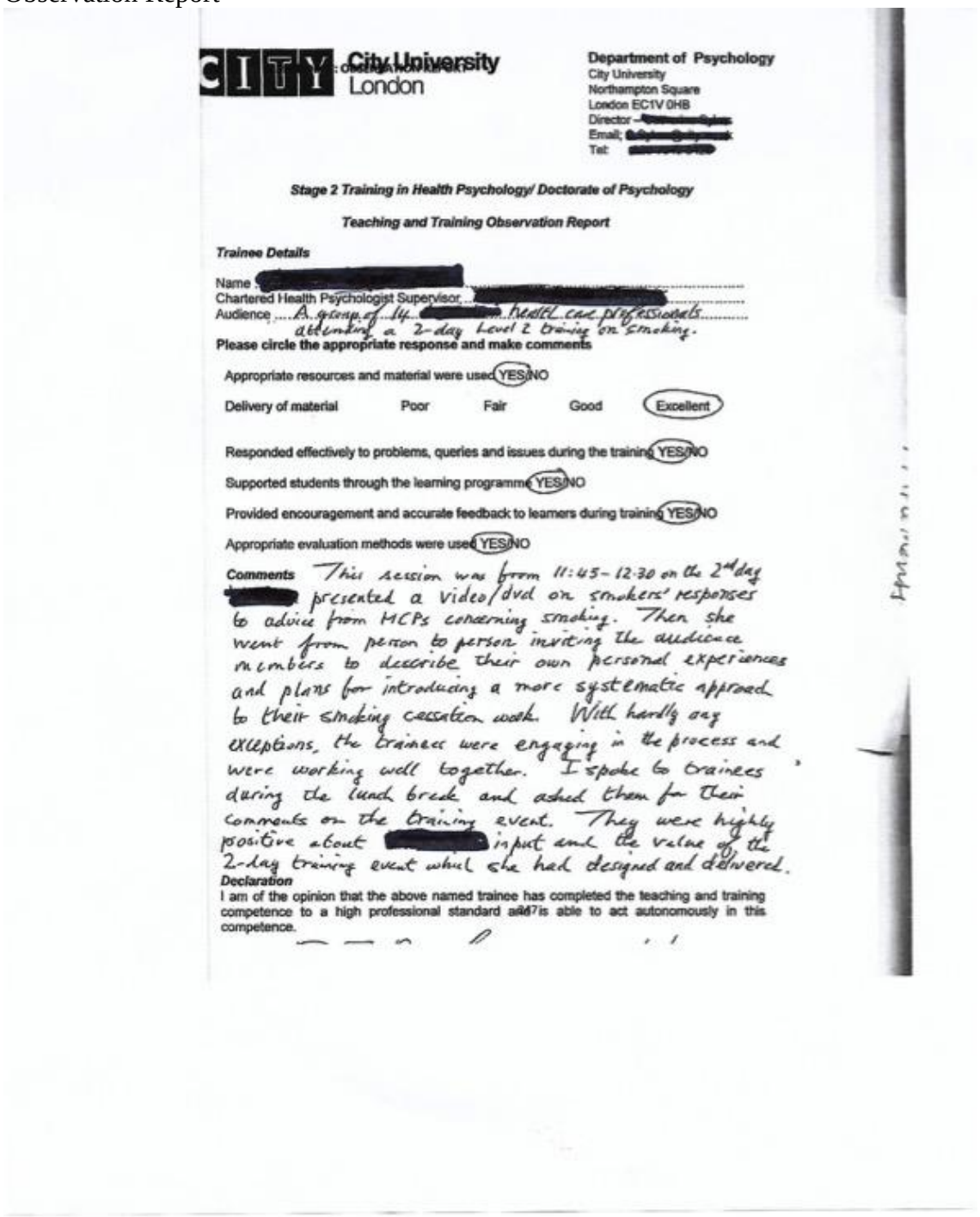


Key: Question 2: following this course do you have a better understanding of what it means to provide intensive one-to-one support to smokers? Question 5: would you recommend this training to your colleagues? Question 6: do you feel the venue was satisfactory for the nature of this course?

Trainees' comments:

- Very informative. Lots of information sheets. Good!
- All the information given was completed satisfactory. The lecturer was very good and knowledgeable.
- Very useful course thankyou
- Everything went smoothly and it was presented in a way that was easy to understand
- Great training. Would happily tell others to come.
- Feel confident after doing this, so thanks a lot
- Really good guidance and lots of useful tips.
- The teacher was very competent and I feel like I have learned a lot today.

Appendix F
Observation Report



City University London

Department of Psychology
City University
Northampton Square
London EC1V 0HB
Director –
Email:
Tel:

Stage 2 Training in Health Psychology/ Doctorate of Psychology

Teaching and Training Observation Report

Trainee Details

Name
Chartered Health Psychologist Supervisor
Audience A group of 14 health care professionals attending a 2-day Level 2 training on smoking.

Please circle the appropriate response and make comments

Appropriate resources and material were used YES/NO

Delivery of material Poor Fair Good Excellent

Responded effectively to problems, queries and issues during the training YES/NO

Supported students through the learning programme YES/NO

Provided encouragement and accurate feedback to learners during training YES/NO

Appropriate evaluation methods were used YES/NO

Comments This session was from 11:45–12:30 on the 2nd day presented a video/dvd on smokers' responses to advice from HCPs concerning smoking. Then she went from person to person inviting the audience members to describe their own personal experiences and plans for introducing a more systematic approach to their smoking cessation work. With hardly any exceptions, the trainees were engaging in the process and were working well together. I spoke to trainees during the lunch break and asked them for their comments on the training event. They were highly positive about input and the value of the 2-day training event which she had designed and delivered.

Declaration

I am of the opinion that the above named trainee has completed the teaching and training competence to a high professional standard and is able to act autonomously in this competence.

Optional Unit 5.1: Implement interventions to change health-related behaviour

Introduction

Smoking is the largest preventable cause of premature death and disability in the UK (Raw, McNeill, & West, 1998) and smoking cessation is a public health priority that has attracted significant government investment for nearly two decades. As well as making stop smoking medications available on prescription, the government has provided funding for campaigns to raise awareness of tobacco-related illnesses and for behavioural support services for smoking cessation activities.

The NHS smoking cessation services integrate a pharmacological intervention, i.e. nicotine replacement therapy (NRT) or Bupropion (Zyban) or Champix, with behavioural support, i.e. 'Withdrawal Oriented Therapy'. The latter provides support in overcoming withdrawal symptoms and the former combats the addictive effects of nicotine. Either of these two interventions when used alone produces improved success rates (NB - success is defined as abstinence for at least 6 months), i.e. success rates with either intervention alone are 12% compared to 5% for quitters using no treatment. The Royal College of Physicians (2000) report that stop smoking groups utilise the benefit of social support in facilitating behavioural change and there is evidence that intensive behavioural support and advice from a clinic run by stop smoking specialist advisors in combination with NRT, Zyban or Champix is the most effective method to help smokers quit (Raw et al., 1998); i.e. when both interventions are used together the success rate increases to 21%.

I completed the Level 3 Specialist Smoking Advisor training in 2004 and in my current role, I facilitate stop smoking groups for [redacted] PCT. The level 3 intervention involves weekly 1-hour group sessions for seven consecutive weeks; this pattern of training provision ensures quitters are supported through the most difficult withdrawal period of stopping smoking.

This case study outlines my experience of being Lead Facilitator of the 7-week group intervention. The clients who attended were either self-referrals or were referred by health care professionals.

Assess the suitability of clients for health-related behaviour Intervention

In the first session clients provide demographic information and complete a clinical assessment form. Their previous history of quit attempts as well as their motivation to quit and contraindications regarding use of NRT etc. are examined in private consultations. At the same time an assessment is made of whether clients are suitable for group treatment, e.g. those who have difficulty hearing, who cannot speak or understand English, who have learning difficulties, who dislike group settings or who have certain types of psychotic illness are screened out and those clients are either offered individual support, are referred on to an appropriate health care professional or will get the support of an individual advisor. (NB in this case study, one client was screened out because of severe alcohol addiction issues, i.e. he acknowledged that he might arrive for group sessions intoxicated and I felt there was a danger that he would be disruptive to the group. I encouraged him to get treatment for the addiction as this would seriously interfere with a quit attempt and I arranged follow-up.

Identify and Negotiate the Behaviour Change Goals of the Clients

The primary goal of the programme is to support clients in achieving complete cessation of smoking from session 3, i.e. Quit Day, and I introduced this goal in the first session. I gained group understanding and agreement to work towards complete abstinence from the designated quit day (i.e. Session 3).

To facilitate self-efficacy and positive expectations of success I explained that the programme is the most effective treatment to help smokers quit (Raw et al., 1998) and that on average, two thirds of participants in smoking cessation programmes stop smoking (Hajek, 1994). This strategy had the intended effect of motivating the clients to take a full part in the programme, which was evident from both verbal and non-verbal behaviours displayed by the participants.

I explained the importance of social support in the process of quitting and achieving complete abstinence from Quit Day and focused on how the shared experience of quitting could help each person manage the withdrawal effects together. One client expressed concern about complete abstinence from Quit Day and articulated his view that gradual cessation was a more realistic goal. In responding to his objection I took the opportunity to explain to the group how reducing the number of cigarettes does not necessarily reduce nicotine intake, i.e. because compensatory inhaling makes each cigarette a more efficient nicotine delivery instrument. I also explained how

reducing the number of cigarettes can lead to greater psychological dependence on the cigarettes smoked. Although these explanations were clearly helpful to other group members who confessed that gradual cessation was initially more appealing to them, the individual who had raised the objection remained unconvinced and he elected to leave the programme, preferring to rely on the "cut down to stop", or "cut down to quit" (CDTQ) "nicotine assisted reduction program. This program is an alternative aimed at smokers who express unwillingness or inability to stop smoking in the short-term; it enables them to gradually cut down their smoking over an extended period while supported by NRT so that they may eventually become able and willing to attempt to quit altogether.

Having established the central importance of social support, I introduced the 'buddy system', i.e. - creating pairs of clients and encouraging them to have daily contact so each participant has constant support and encouragement. For those who decided to adopt the buddy system I explained the associated betting game as outlined by May and West (2000), i.e. - a bet placed by one buddy is lost in the event of the other buddy smoking.

To further enhance the social support effect, I asked each client to make a commitment to the group that they would remain completely abstinent and I also suggested that they should tell their family and close friends that they were stopping smoking (USDHHS, 2004). Most of the group responded positively to the latter suggestion but (for reasons that they were not inclined to share) 2 people indicated that they would not be informing their family.

Introducing Smoking Cessation Aids

I provided clients with a description - including the possible side-effects as described by Hajek (1994) - of the available pharmacological treatments (NRT & Zyban) and I allowed them to examine the six NRT products. I presented the findings of Silagy and his colleagues (2008) that people are more likely to quit with pharmacological support but also made it clear that adopting a medical aid to assist cessation was not a requirement for taking part in the programme. I explained that if they decided to use a medical aid they would have a major input in deciding which treatment they would use, pointing out how both NICE (2002) and leading researchers (Raw et al., 1998) have concluded that selection of the NRT product is best determined by a client's personal preference and tolerance of the side effects.

Three clients expressed concerns about using NRT because they viewed it as either creating a new addiction or feeding an existing one. In relation to the former objection I explained that it wasn't creating a new addiction by explaining how smokers already had an addiction to nicotine. To address the concerns about feeding an addiction I referred back to comments many of the participants' had made about how withdrawal symptoms had been too difficult to manage. I explained how the NRT reduces withdrawal symptoms such as anxiety and irritability which in turn allows them to focus on the behavioural aspects of smoking and ultimately to change their behaviour and stop smoking.

For the clients who elected to use a medical aid, I wrote prescription requests addressed to their GPs together with any relevant information, e.g. one client, John, was taking medication, (Theophylline), for a recent Asthma attack and his prescription request explained that his dose would need to be reduced because smoking cessation would cause increased plasma levels.

Assess the Cognitive, Behavioural and Situational Determinants of and Influence on Relevant Current Behaviour & Develop a Behaviour Change Plan

One of my key and enduring roles throughout the programme was to facilitate client understanding of the obstacles that threatened to derail their continued abstinence and to identify how to remove those obstacles. I worked to achieve these related goals by engaging with each individual and encouraging them to reflect on how they could act to overcome their barriers to continued abstinence. I also worked with the group directing discussions about how obstacles could be removed and encouraging them to examine and correct false beliefs and misconceptions about the role and effects of smoking behaviour. The clients' smoking diaries were an important source of information in identifying obstacles to remaining abstinent and this information, combined with individual and group discussions, produced a list of factors/situations that had prompted people in the group to smoke. The list included: (a) anxious and/or stressful environments, (b) boredom, e.g. during work breaks, (c) fatigue, (d) relaxing after a meal, (e) being with others who are smoking, (f) anger, frustration or irritability and (g) drinking alcohol (either at home or in bars).

I guided the group in an examination of each situation with the goal of improving client insight into how the strong impulse or urge to smoke emerged. After this I encouraged them to think creatively about practical and realistic ways in which

they could combat these impulses and urges. This generated a variety of remedies ranging from using nicotine inhalators and avoiding certain situations, e.g. - bars, to learning stress reduction techniques and using unpleasant visualisations of how the smoke was attacking their lungs. Each client resolved to try at least one strategy and report back on its success. To further add to the clients behaviour change plans, I introduced the group to urge control strategies: (a) Delay acting on the urge to smoke, (b) Diaphragmatic breathing, (c) Drinking water and (d) Distraction. Most of the group found at least one of these attractive and resolved to try them.

The importance of having motivators and rewards for maintaining complete abstinence was discussed and reviewed throughout the programme. Most of the group mentioned the financial pain associated with their smoking habit and were keen to explore how money saving could be used as a motivator and reward. I used anecdotes from previous groups to illustrate how substantial amounts of money could be saved and used for rewards. I gave as an example, a client who had bought himself an Apple computer and another who had used savings to take herself and her daughter on a trip to America. These commentaries were very well received and resulted in most of the group calculating how much they could save and what they could buy.

The primary goal of complete abstinence was re-stated and emphasised in every session - this was articulated as "the not even one puff rule". Clients who started smoking between sessions but stopped again were encouraged to think of it as a 'slip' and not a relapse - they were encouraged to return to the group and modify their coping strategies. However, to avoid having a possible negative effect on the group, those clients who re-started smoking and had not stopped were encouraged not to return to the group - in this group only one client left for this reason.

Ensure Monitoring and Support for Behaviour Change Plan

The Smokerlyser machine detects levels of carbon monoxide (CO) in the blood through exhaled air - these levels are several times higher for smokers than for non-smokers and the machine provides a reliable way of identifying if a person has smoked. At the start of each session after Quit Day, clients are asked whether they have remained abstinent and they are asked to blow into a Smokerlyser machine to determine whether or not they have smoked between sessions. The Smokerlyser is a motivational tool in two respects: first, it encourages complete abstinence by virtue of its ability to detect if a client has had even a single puff between sessions. Second, it provides

objective evidence of the health benefits of complete abstinence, i.e. the reduction to normal levels of a poisonous gas (i.e. CO) in the lungs (Raw et al., 1998).

As well as monitoring CO levels, the weekly sessions serve to support clients in overcoming any difficulties they have encountered in their quit attempts. My role in each of the last four sessions is to facilitate a sharing of client experiences of remaining abstinent over the previous week. As well as providing positive feedback in relation to successes, this involves encouraging clients to examine how they managed (or failed to manage) any difficulties that arose in the previous week. Encouraging clients to engage in self-monitoring is important because it enables them to reflect on their performance and to undertake action planning for improved future success. Previous research Sniehotta, Scholz and Schwarzer (2005) posits that that the 'intention-behaviour gap' which refers to the incongruity of intending to change behaviour but not being able to accomplish it, is less likely to occur when detailed action planning, perceived self-efficacy and action control are all present in the process.

Evaluate Outcome

The success rate (success being defined as not a single puff of a cigarette for the last 14 days) was 66% which is higher than the 56% for all Stop Smoking Services between April 2004 and March 2005 as reported by the NHS (West, Walia, Hyder, Shahab, & Michie, 2010). However, this NHS figure is based on group and individual treatment taken together, i.e. - national data based on group treatment alone is not available. The outcome rate of 66% is similar to the figure of 68% as reported by Hajek (1994) for withdrawal orientated therapy, where success was defined as no smoking for at least the last 7 days of treatment provided.

In their final session clients completed a feedback questionnaire that was designed to identify the effective components of their behaviour change process. The factors clients identified as important included the support of the group and the feeling of social responsibility to the group, i.e. most clients reported that they did not want to let the group down and in particular - their buddies. A majority of the clients also identified the advice, support and guidance received from the advisors (particularly in relation to explanations about managing the side effects and withdrawal effects) as important factors in their success.

Negotiate Completion, Follow-Up or Referral as Appropriate

Relapse prevention groups are held every 7 weeks at the end of each clinic. These are open to all clients who have successfully completed a group and have remained abstinent. At the end of 1 year these clients are awarded a certificate and an engraved silver pen.

At 1 year follow up, 27% of those clients who made the quit attempt reported remaining abstinent. Although this is only a small proportion of those who made the quit attempt, it is nevertheless higher than the one year outcomes for the NHS specialist services as reported by Ferguson et al., (2005). Furthermore, the relapse rate of 73% for this group is consistent with published studies (Stapleton, 2001) and clinical trials (West, McNeill, & Raw, 2000). The relapse rate is, however, high and it presents a problem for interventions such as the one described here - the obvious criticism being that the programme is not doing enough to combat relapses. Unfortunately, there is currently a lack of evidence of efficacy in relapse prevention methods for people who stop smoking and there is a pressing need for further research in this area.

Those clients who failed to successfully complete the programme were contacted and either referred on or offered support.

Reflection

Following 'Quit Day' I found the weekly task of explaining to clients their experiences, e.g. how factors causing them to smoke were operating, particularly difficult because of concerns I had that participants would interpret my explanations as either devaluing their experience or as evidence that I did not understand their experience.

I also had some apprehension in relation to offering practical solutions for overcoming barriers to complete cessation because those suggestions seemed to me to be obvious, i.e. I expected that most of the participants would have tried them and would therefore feel the programme had little to offer them. I successfully resolved the latter concern by engaging the group as a whole in the process of generating practical advice. This proved to be an important learning experience for me because I discovered that blending my suggestions and comments into the general group discussion promoted greater client ownership of that information, i.e. clients perceived themselves as producing the ideas (including those I contributed directly) and they perceived my role as simply facilitating and validating that process. The strategy was also effective for

explaining client experiences, i.e. I initiated group discussion by inviting clients to both share their personal experiences and to offer explanations for experiences presented by others and once started I made contributions and suggestions to guide them towards psychologically valid explanations.

Another strategy that I discovered was a very powerful and versatile tool for helping clients to understand their own experiences was providing anecdotes of other clients experiences. Explanations of how previous clients had come to accept certain explanations of their experiences as valid was very engaging for the group as a whole; they enjoyed the story telling and were very keen to volunteer how the explanations presented made sense in terms of their experiences and once again I was able to provide suggestions and comments to facilitate psychological insights.

I found the idea of excluding clients following a relapse particularly difficult because, in spite of the additional support I could offer, I felt such clients would inevitably interpret exclusion as evidence of their failure. However, as a result of reflecting on this and talking to more experienced advisors I came to terms with this responsibility and by the sixth session I felt much more comfortable discussing how a relapsed client should exclude themselves from the programme. This change was the result of rehearsing explanations of how a relapse was evidence of not being ready for complete abstinence at that time but not evidence of failure in an absolute sense; these rehearsals convinced me which made it easier to convince clients.

Another difficulty that I experienced and was able to successfully resolve was my lack of personal belief in the buddy system. As I am someone who would not naturally respond to this strategy it was uncomfortable and challenging to present it with conviction to the group. I decided to gain first-hand experience of the buddy system and engaged another psychologist, who was also sceptical of it, in a buddy system that continued over the last 4 weeks of the programme. I found this experience very useful and as a consequence of it I now feel very comfortable presenting the buddy system to clients and encouraging them to use it.

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Optional Unit 5.2: Directing Stop Smoking Interventions of Health Professionals in Primary Care

Needs Assessment Report: Establishing Needs & Implementing Strategies for the Procurement of Intervention Resources

Background Information

That more than a quarter of the adult population of the UK smoke is itself a bleak fact but in one deprived East London borough, 40% of the 249 000 borough residents are categorised as smokers (Health and Social Care Information Centre, 2005). Unsurprisingly, smoking related deaths and illnesses in this borough are significantly higher than the national averages for England and Wales. More worryingly the number of women residents of this borough who smoke during pregnancy is 9% higher than the national average, i.e. 37% of women in the borough smoke during pregnancy.

Current Smoking Cessation Provision

Smoking Cessation Services in the borough are based on the current evidence for effectiveness in delivering smoking cessation support to smokers; i.e. the smoking cessation guidelines published in Thorax in January 2001 highlight the incremental effects that evidence-based smoking cessation interventions can have on abstinence rates for six months or longer. The key component of the interventions is behavioural support combined with Nicotine Replacement therapy (NRT) or Buproprion (Zyban) and the Cessation Service uses three levels of intervention, Brief, Intermediate and Specialist.

Brief Intervention (L1)

This intervention level involves a Health Professional spending up to 5 minutes encouraging the smoker to quit and it is based on the '5A Model':

- Ask.
- Advise.
- Assess.
- Assist.
- Arrange.

This intervention results in up to 3 out of 100 smokers stopping smoking for at least 6 months (Whitlock et al.2002).

Intermediate Intervention (L2)

This intervention involves the provision of evidence based smoking cessation support through a combination of pharmaceutical treatments and behavioural modification guidance. Clients are offered a 20-minute session of smoking cessation support once a week for 5 weeks (up until 4 weeks after the quit date). Health Professionals delivering this intervention are required to practice to a minimum standard by adhering to a service treatment protocol.

Specialist Intervention (L3)

This level of intervention is provided via a service level agreement with the [redacted] Hospital; the hospital provides one to one sessions and group therapy, which are conducted within the hospital itself and at a satellite clinic, i.e. a local GP Surgery. Based on outcome data generated between 2001 and 2004 their quit rate was c40% higher than the national rate, i.e. 68% compared with a national rate of 48% ([redacted] NHS Trust [redacted] smoking cessation clinic (2004).

Establishing Needs

Since their creation Smoking Cessation Services have been rigorously monitored by the Department of Health. In 2005 targets were set at 4,556 quitters to be achieved over a 3-year period ending in April 2008, which required the service to both expand and increase its throughput.

The Stop Smoking Service Core Specialist Team consists of a Stop Smoking Service Co-Ordinator, a Primary Care Facilitator, an administrator and three Stop Smoking Service Specialist Advisors. Because the Core Specialist Team could only provide support to a limited number of smokers it was necessary, in order to assist the PCT to reach its quitter targets, to extend the availability of smoking cessation services across the borough. Because most contact between patients and the NHS take place within primary care services this arena was ideal for delivering smoking cessation advice to most smokers over the course of a year (Health Development Agency, 2003a;8). To extend the service and reach the maximum number of smokers a range of healthcare professionals were given specific training and guidance to offer smoking cessation services within the borough.

In February 2005 the Service was approached by the Neighbourhood Nurse Leads (NNL's) with a request to provide Smoking Cessation Training for community nurses, i.e. district nursing and health visiting teams. Community nurses routinely provide their services to people who have smoking related diseases such as chronic obstructive pulmonary disease (COPD) as well as smokers who are parents of young children and people who are not registered to GP practices. This professional group clearly had a very pressing need for the training they were seeking as well as practical support and resources to set up specialist smoking cessation clinics.

The proposal was to provide an Intermediate Intervention Service (L2) (a neighbourhood clinic) in each neighbourhood (i.e. 1-4), which would be staffed by community staff, i.e. District Nurses & Health Visitors. The service was to be health centre based and aimed to complement the existing intermediate services (provided by Practice Nurses and pharmacies) and would make smoking cessation services available to:

- People not registered with a General Practice;
- People registered with a General Practice that was not providing Smoking Cessation services; and,

- Housebound individuals.

The project would be known as the 'Stop Smoking Services in Community Health Services Project' (SSSCHSP).

Procurement of Resources for the Planned Intervention

Once the need for the SSSCHSP was established I proceeded to focus on the procurement of resources necessary for implementing it. Following consultation with members of the COPD clinical panel and key Professional Executive Committee (PEC) members (January 31st 2005), the COPD clinical panel agreed that £10,000 should be provided from the Local Development Programme (LDP).

I reviewed the resources that were required for the proposed interventions and acted to ensure that they were appropriate and adequate for the SSSCHSP; these resources are outlined below:

STAFF

Neighbourhood Nurse Leads (NNL's) agreed that staff interested in smoking cessation would attend training for Brief and Intermediate Level Interventions. Following negotiations with the Associate Director, Modernisation and Organisational Development in the PCT, I secured agreement to have this training provided as a Protected Learning Time (PLT) event. Training subsequently took place on a monthly basis (between March and June 2005) at a local venue; on completion staff signed a service level agreement, i.e. a contract binding the procurement of their services.

TRAINING

Smoking Cessation training adheres to established evidence-based practices for the provision of smoking cessation services in primary care. The guidelines are provided in The Standard for Training in Smoking Cessation Treatments (Health Development Agency, 2003) and 'adequate training' is defined as follows:
Brief Intervention: A 2-hour block of training, based on the 5 A Model, which would encourage smokers to stop smoking and signpost them to the neighbourhood clinics. Approximately 10 community staff per month would receive this training.

Intermediate Intervention: A 1-day training programme based on The Department of Health Standard for Training in Smoking Cessation Treatments. Eight community nurses, would receive this training

EQUIPMENT

The equipment necessary for implementing the intervention included Spirometry filters and Carbon Monoxide Monitors (appendix A).

Why this equipment is important? Measurement of exhaled carbon monoxide (CO) concentrations via a carbon monoxide monitor is a recognised objective measure of abstinence; it provides the Health Professional with a non-invasive method of assessing smoking status and has been found to increase the number of clients who complied with advice to quit (Middleton & Morice, 2000).

It has been shown that diagnosis of airflow limitation combined with smoking cessation advice increases stop-smoking rate (Dorota Górecka et al., 2000). Spirometry filters allow the measurement of pulmonary lung function and published guidelines recommend spirometry as both an objective measure of pulmonary function and a means of diagnosing chronic obstructive pulmonary disease (Celli & MacNee, 2004)

VENUE

One venue in each of the 4 neighbourhoods was secured following negotiations with the 4 Neighbourhood Managers and the Health Centre Practice Managers within the borough.

A Plan of Supervision for the Intervention: assessing the capabilities of the people required to conduct & monitor the intervention

Developing Competencies Required to Deliver the Intervention

Developing a list of competencies required to deliver Smoking Cessation was a key task; these competencies, i.e. the skills, knowledge and attitudes needed to conduct the tasks and functions of smoking cessation support, were developed from the International Cessation Competencies accepted by the Association for the Treatment of Tobacco Use and Dependence (2005) and they were constructed around the evidence based guidelines. Being primarily skill or knowledge based the competencies are measurable, observable and relevant to implementing the intervention; they benefit the advisors because they serve as a roadmap for their skill development. (**appendix B)** I judged that the Competency standards would help maintain public confidence as well as ensuring quality and consistency across the service; furthermore, they would also ensure that service users received appropriate management and optimal outcomes.

Training Needs Analysis

Prior to the delivery of the training I conducted a training needs analysis (March 30th 2005) which involved organising a focus group with the relevant key stakeholders (NNL's and Community nurses), this established that the key training requirement was the 'technical' competencies specifically relating to cessation. I took advantage of the focus group activity to secure the engagement, motivation, personal involvement and commitment to the project as whole.

Seeking Appropriate Personnel for Training.

I gained agreement from the Neighbourhood Nurse Leads (NNL's) that all Community Nurses would deliver Brief Intervention (L1) and related training and this would be mandatory. Eight nurses expressed interest in providing the Intermediate Intervention (L2), which was a sufficient number to cover the 4 clinics that needed the service one day per week; the 8 available nurses ensured that we had extra staff to cover absences, e.g. absences arising from sickness and annual leave. The training schedule was developed and given to the NNL's.

Training Nurses to Achieve the Competencies to Conduct the Intervention.

The competencies translated readily into learning outcomes for training, which was devised and conducted in line with the Department of Health Standard for Training in Smoking Cessation Treatments (2003). Community nurses were trained throughout the year 2005/6 to provide brief intervention (level1) (approximately 10 nurses each month) and 8 nurses in total were trained to deliver Intermediate smoking cessation intervention (L2). As well as equipping trainees to carry out the intervention the Intermediate Smoking Cessation Intervention Training (L2) incorporates assessment of competencies achievement; e.g. knowledge quizzes, observations of performance, simulated practices and role-playing, and certification is based on adequate competencies achievement.

Following training, trainees signed a service level agreement that stipulated their responsibilities as a L2 advisor including post training requirements. Trainees are required to attend update training sessions every six months in order to maintain and develop their clinical skills (**Appendix C**)

Advising and Guiding the Activities of Designated Others

Level 2 trained nurses were provided with Carbon Monoxide monitors and mouthpieces.

Nurses were provided with training resource packs appropriate for delivering a weekly smoking cessation intervention. Level 1 providers were equipped with the necessary protocols and information to signpost to Level 2 services. Level 2 provider packs contained weekly protocols and hand-outs together with my contact details and administrative paperwork.

Level 1 providers were able to implement brief opportunistic advice immediately as this could be incorporated into their day-to-day clinical role. They detailed the provision of the intervention in their clients' notes in order to aid the monitoring and feedback process.

I provided the nurses with post training support on an individual basis for two weeks after they completed their training, which enabled them to:

- Examine specific skills, e.g. using the carbon monoxide monitor;
- Explore ideas/ misconceptions;
- Discuss problems/concerns and practicalities of conducting the clinic; and,
- Further develop personal style regarding supporting clients.

At the end of the training all the advisors demonstrated competence although two expressed a lack confidence in their ability to deliver the service. To address this issue, I agreed with the two in question to conduct observations of their clinics and provide constructive feedback; they agreed to produce self-assessments as part of this process. In providing the feedback I was mindful of the need to build their confidence and I therefore limited my comments to 3 or 4 points on which improvements could be made. This proved a successful strategy and when more points needed attention I was able to pick them up in subsequent feedback sessions.

As part of a Service Level Agreement the nurses agreed to take part in training updates and to make full use of a training handbook. They were supported by having access to me for:

- Discussion of any problems/complex cases;
- 1-2-1 supervision as needed; and,
- Monthly group supervision over a 6 month period.

To ensure a safe environment for group supervision I agreed explicit boundaries, i.e. the ground rules were developed in the 1st session, i.e. a working agreement between the community nurses and myself (**Appendix D**).

In response to concerns expressed about clinics being rushed and possible poor attendance at clinics I took appropriate action to ensure that the practices adhered to agreed time slots and that appropriate advertising was in place e.g. leaflets in health centres. I was then able to reassure the Nurses that their concerns had been addressed. I explained to the nurses the complaints procedure to be followed by their clients, which was detailed on the back of patient leaflets, and explained how completed complaint forms could be sent to NNL's via Neighbourhood Manager's based in the Health Centre's.

Confidentiality and consent policies were discussed and fully acknowledged by the Nurses who, as professionally registered nurses, were used to working within the Caldicott Guidelines (1997).

Conciliation and arbitration in cases of disagreements about practices, procedures and outcomes were also discussed. The nurses were members of the Community Practice Association (CPA) or The Royal College of Nursing and these issues would be dealt with via these Professional organisations. I provided them with

the starting dates of the clinics, and we agreed dates for group clinical supervision (**Appendix E**).

To Ensure Technical Support for A Planned Intervention

As accurate and reliable carbon monoxide monitors and their correct use throughout the planned intervention was central to the intervention process, I implemented a close management of both the delivery and use of the monitors. I took personal responsibility for procuring the monitors in good time and for checking that they were in good working order on delivery. To ensure that all the L2 advisors used the monitors correctly I provided them with following services/support:

- Written and verbal guidance on the correct use of the monitors;
- Practice in the use of the monitors
- Demonstrations of correct use with 'live' clients, i.e. the L2s shadowed me while I used the monitors with my clients
- Ongoing telephone support throughout the intervention period.

To maintain optimal performance from the monitors I instructed the L2s to return the monitors to me for recalibration after a 6-month period. I provided the L2s with pre-franked envelopes for this purpose and contacted them at the end of the 6-month period to ensure compliance with this procedure. Furthermore, I organised replacement monitors, which I checked prior to despatch to the L2s to ensure the service provision was not disrupted during the recalibration process. I ensured that all the L2s had telephones, i.e. provided by the PCT, so that they were able to conduct telephone counselling and 'follow-ups'.

To Oversee & Direct the Conduct of the Planned Intervention.

The Smoking Cessation Clinics started on April 11th 2005; two centres conducted early morning clinics and two afternoon clinics. Initially the L2 advisors shadowed me as I provided the smoking cessation support but by June 22nd 2005 they were all running the clinics. From June my role was to continually monitor the intervention process to ensure it was provided competently, effectively, ethically and in accordance with the SLA service protocol and code of conduct; this monitoring involved examining the monitoring form returns. I made continual checks to ensure patient data was stored correctly and rules of confidentiality adhered to. When there was evidence that aspects of the intervention were not well understood I took appropriate action. For example, on discovering that some of the nurses were not following the programme as strictly as was required I addressed the issue in supervision; I focused on improving their understanding of the processes underlying behaviour change and maintenance so they had a greater understanding of the importance of adhering strictly to the programme.

Reflective Analysis

Problems encountered in Implementing the Intervention and Supervising its Implementation

Implementation

In considering how to implement this intervention I was particularly mindful of the need to:

* Integrate both local and national contexts in the structure of the intervention;
* Establish good working partnership with key stakeholders and community nurses;
* Incorporate knowledge of the community's needs; and,
* Fully utilise the existing skills and resources available in the community.

The attention I gave to these issues was a key determinant in what proved to be a competently planned and effectively delivered intervention. In addition to addressing all the important issues the intervention very effectively targeted members of the community who most needed it, e.g. people whose chronic health problems were deteriorating due to smoking and who, as a result of the intervention, gained health improvements. Furthermore, the intervention helped the stop smoking service increase its throughput and brought the Stop Smoking Service closer to achieving its DH targets, which in turn allowed me to carry out one of my key duties, i.e. publicising the fact that targets were being met.

Although aware at the outset that this project was complex on reflecting I realise that I underestimated how challenging it would be to take the Lead, particularly as I had no previous experience in this role. The most demanding element of the process was managing and directing the Nurses, which at times caused me significant stress and anxiety. With the benefit of hindsight, I realise that, in terms of the time and effort that was required to lead, it was simply too much for one person. It was however a very beneficial learning experience; I have gained a good understanding of how critical it is to focus maximum attention, in the planning stage, on all possible contingencies regarding people management skills when directing complex interventions.

Monitoring the intervention: data quality, collection and returns

I asked advisors to complete monitoring forms that I had designed to record essential information, i.e. client demographics, number of cigarettes smoked, time to

first cigarette and Carbon monoxide readings. This monitoring procedure proved only partially effective, i.e. many of the forms were not completed correctly, and I was subsequently involved in a very time consuming process of gathering the missing data. In discussing this issue with the nurses, it became clear to me that in the initial training I had failed to emphasise sufficiently the importance of the monitoring and data collection requirements. Approximately six weeks into my role I successfully resolved this problem by providing all nurses with a laminated template of a correctly completed form together with an emphatic explanation of the importance of comprehensive and accurate data collection.

I learnt from this experience the importance of giving more time and effort at the start of an intervention to the provision of specific guidance on monitoring form completion.

Resources continual supervision.

Continual supervision presented me with time management issues because of the number of tasks, including:

- Observing clinics;
- Running clinics;
- Monthly supervisions;
- One to one supervisions;
- Supplying, calibrating and checking equipment;
- Phone support; and,
- Travelling.

These tasks combined with my normal work activities produced a very challenging work load for me, and one that would not be sustainable in the long term, i.e. an intervention on this scale requires more than one supervisor.

Supervision

Supervision of the nurses was challenging but enjoyable and rewarding. The challenges included working to ensure that the nurses normal duties and clinical responsibilities did not compromise their work in smoking cessation; establishing close working relationships with the NNL's to address this was a very rewarding experience.

Co-ordinating the diaries of 9 people was challenging and finding a remedy, i.e. providing a limited number of alternative dates but with a long notice period, was very rewarding. Stimulating and mutually beneficial discussions of the complex needs of patients and the skilled responses required in supporting them as well as the rich exchange of views, ideas and perspectives was very rewarding. Equally rewarding was the fact that feedback I provided was taken on board and appreciated, which was evident from the warmth and positive non-verbal behaviours displayed, e.g. good levels of eye contact, smiles and head-nodding. I gained an enormous amount from this project; knowledge, skills and confidence both generally and in the context of directing the implementation of interventions has improved far more than I could have anticipated.

References (Optional 5.2)

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Appendices for optional unit

Appendix A

EQUIPMENT & RESOUCES PROCURED FOR SSSCHSP

Spirometry filters for GP practices.
Carbon Monoxide Monitors.
12 boxes of mouthpieces.
4 packets of replacement valves.
4 recalibration kits.
Training and resource packs.
Leaflets and posters, i.e. for the promotion and marketing of the service to staff and users.

Appendix B

(COMPETENCIES)

Standard 1: Ask smokers if they are currently smoking*

1.1	Ask about & document a client's current smoking status & details	Core
1.2	Access reliable information about smoking addiction, in relation to the Stop Smoking Service Protocol	Core
1.3	Demonstrate knowledge of smoking addiction as a chronic relapsing condition.	Core
1.4	State the prevalence and patterns of smoking in England	Core
1.5	Demonstrate awareness of the historical, political, social & economic factors that promote & maintain smoking in England	Core
1.6	State the major harmful health effects of smoking on individuals, pregnant women & their babies and the wider community, and the health benefits of stopping smoking.	Core
1.7	Identify the importance of complete cessation from as early in pregnancy as possible for pregnant women who smoke	Core
1.8	Ask all people documented as smoking, at each admission to hospital and each presentation to a primary care setting, if they are still smoking.	Core

Standard 2: Give Brief Advice

1.1	Give brief advice clearly and convincingly, and document that this has taken place.	Core
2.2	Demonstrate knowledge that giving brief advice to stop smoking is an effective and cost-effective strategy to promote quit attempts.	Core
2.3	Demonstrate knowledge that brief advice can be given to people who smoke often and at any time, regardless of the client's readiness to stop smoking.	Core
2.4	Demonstrate knowledge that giving brief advice can be anything from 30 seconds t a few minutes	Core

Standard 3: Provide Cessation Support

3.1	Assess a client's interest in receiving cessation support	Core
3.2	Refer clients to specialist cessation support, a medical practitioner, or quit-lines if appropriate	Core
3.3	Identify common myths about nicotine, nicotine addiction, smoking & its treatment.	Core
3.4	Demonstrate empathy regarding nicotine addiction.	Core
3.5	Understand the need for medications to deal with the symptoms of withdrawal.	Core
3.6	Assess the level of nicotine addiction using 'time to first cigarette' and use this to help plan treatment	Generalist
3.7	Demonstrate knowledge of the characteristics (types, costs, sources, doses, actions, effectiveness & side-effects) of effective stop-smoking treatments available in England	Generalist
3.8	Identify complementary therapies for stop-smoking treatment and understand their effectiveness.	Generalist
3.9	Negotiate cessation goals 7 strategies with clients, including setting a target Quit Day	Generalist
3.10	Demonstrate knowledge of or ability to use an effective behavioural support method in line with psychological theories	Generalist
3.11	Offer nicotine replacement therapy (NRT) and understand the use of higher doses and combinations of NRT (eg, patches& gum) when appropriate.	Generalist
3.12	Refer to a medical practitioner for prescription only medications i.e. bupropion, varenicline and other forms of NRT (eg, inhaler) when appropriate.	Generalist
3.13	Arrange follow-up support during treatment	Generalist
3.14	Identify the common symptoms of nicotine withdrawal.	Generalist
3.15	Identify the common cues that trigger urges to smoke.	Generalist

3.16	Demonstrate knowledge of common smoking compensation behaviours	Generalist
3.17	Demonstrate knowledge of basic relevant anatomy and physiology, particularly the areas of the brain involved in reward and dependence, the lungs and cardiovascular system.	Generalist
3.18	Verify self-reported abstinence using a Carbon Monoxide Monitor where available & feasible.	Generalist
3.19	Understand measure & document treatment endpoints.	Generalist
3.20	Work with clients using appropriate strategies to help them maintain abstinence.	Generalist
3.21	Demonstrate ways in which services can be promoted and delivered to attract the community.	Generalist
3.22	Demonstrate the need to seek expert advice for managing complex cases, such as clients with mental health illness, concurrent alcohol and other drug addiction problems or a co-existing medical disorder.	Generalist
3.23	Conduct a risk-benefit assessment with pregnant women who smoke to help determine safe and effective treatment.	Generalist
3.24	Use stop-smoking medications in clients with cardiovascular disease and other co-existing medical conditions, pregnant women, and users of mental health and addiction treatment services, especially those with complex psychological disorders.	Specialist
3.25	Identify the effects of smoking on the metabolism of certain medications (eg, those used to treat people with mental illness, asthma & diabetes), and the changes seen when stopping tobacco use	Specialist
3.26	Follow & document steps in addiction assessment and treatment planning, and collect data on the cessation service provided to allow standard monitoring of clients & service effectiveness	Generalist
3.27	Use more than one effective behavioural support method in line with psychological principles.	Specialist
3.28	Provide ongoing support for clients for at least one month	Generalist
3.29	Demonstrate knowledge of and ability to treat nicotine addiction long term.	Specialist

Appendix C

APPENDIX C

Service Agreement between

[redacted]

Stop Smoking Service

And

Surgery:

Surgery Address:

For the period

1st April 2005– 30th June 2006

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AGREEMENT FOR PROVISION OF A STOP SMOKING SERVICE BY GP PRACTICES [redacted]

THIS AGREEMENT is dated 2005

Between:

(i) [redacted] **CARE TRUST** of [redacted]

[redacted];

And:

(ii) Of

(" The Provider")

1. **AGREEMENT PERIOD**
The agreement will commence from the date of signature and remain in force up to 30th June 2006.

2. BACKGROUND

A. [redacted] has specific targets to meet with regards to reducing inequalities in the borough and one of the priorities to help smokers to achieve long-term abstinence from tobacco products.

B. [redacted] has agreed that empowering accredited GP PRACTICES to supply and advise on smoking cessation will help smokers to achieve long-term abstinence from tobacco products.

C. The provider has agreed to provide smoking cessation services on the terms and subject to the conditions set out below.

IT IS AGREED **as follows:**

3. DEFINITIONS

Appendix D

Agreed Ground Rules/Working Agreement for Group Supervision

All meetings to follow the agreed comprehensive boundaries

Confidentiality
All issues raised to be treated as confidential.

Timings
To meet every 5 weeks routinely; any changes to this schedule to be discussed and agreed.
Sessions will usually be of 1.5 hours duration.

Sensitivities
Everyone in the group to treat each other with respect & sensitivity.

Clarifying
Questions and comments welcome and encouraged as a means of ensuring group members gain clarity on and good understanding of the all issues discussed.

Explore/Challenge/Probing
Supervisor to encourage reflection and learning by exploring issues & providing feedback in relation to subjects and material discussed.

Non-Judgemental
The relationship between the supervisor and the group to be such that discussions take place openly and freely without either the supervisor members of the group being judgemental of each other. The supervisor will facilitate different perspectives and provide feedback on given topics in order to allow and actively promote refection and learning within the group.

Agenda Items
It is the responsibility of each supervisee to bring to the session any practice concerns.
The Supervisor will lead discussions and provide mentoring and feedback.

DNA Policy
Supervisees must give prior notice and apologies if they cannot make the group supervision. Supervision will be cancelled if in exceptional circumstances the Supervisor is unable to provide the supervision.

Mobile phones are to be on silent at all times.
The Supervisor has agreed to provide refreshments for each session.

Appendix E

Date	Hrs	No. Present	Supervision Focus
9/5/05	1.5	8	Ground Rules • Planning for use supervision. • Supervision needs. • Practice Issues/Case histories & discussion. • Use of NRT & other aids, combining products & procurement of samples • Gaining client rapport • Agenda setting for next meeting
6/6/05	1.5	8	Practice Issues/Case histories & discussion. • Effects of smoking on metabolism of medications • Emotional regulation • Smoking lapses • Co-morbid psychiatric disorders/co-existing medical disorders & tx choice • Referring clients on to specialists. • Monitoring form completion • Discussion about latest research • Agenda setting for next meeting
4/7/05	1.5	6	Practice Issues/Case histories & discussion. • Implementing the diary aspect of the Intervention for behaviour modification • Use of behavioural contracts • Monitoring form completion • Agenda setting for next meeting
1/8/05	1.5	8	Practice Issues/Case histories & discussion.. • Importance of building client self-efficacy • Client preparation for 'vulnerable' situations (relapse) • Developing appropriate coping skills in clients • Agenda setting for next meeting

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29/8/05	1.5	7	Practice Issues/Case histories & discussion.. • Relaxation exercises • with stress training or anger management techniques • Referring the client to other agencies • Agenda setting for next meeting
26/9/05	1.5	8	Practice Issues/Case histories & discussion.. • Reinforcing client success • Principles of reinforcement for behavioural modification • Helping clients build in schedules for self reward for not smoking. • Planning for future use of group supervision

SECTION D – SYSTEMATIC REVIEW

Qualitative Meta-synthesis of Patients' Perceptions and Experiences of Mindfulness -Based Stress Reduction or Mindfulness-Based Cognitive Therapy as Adjunctive Treatment for Cancer Patients

Abstract

Background

Almost half of cancer patients have experienced psychological distress and difficulty coping post-diagnosis. Given that the psychological trauma has not, until relatively recently, been addressed by orthodox medical interventions, it is unsurprising to find that cancer patients have reported high levels of dissatisfaction with the care they have received (Ashbury et al., 1998). National Health Service guidelines suggest that complementary therapies and psychological interventions should be integral to patient support. One of the most promising therapies in terms of modifying psychological distress and improving health related quality of life (HRQoL) among cancer patients is mindfulness (Carlson & Garland., 2005; Ledesma & Kumano., 2009). Although in recent years there has been some qualitative research published on mindfulness-based interventions (MBI's) there is, as yet, no cumulative body of knowledge about, or theoretical understanding of, mindfulness.

The aim of this meta-synthesis was to provide an integrated description and interpretation of cancer patients' perceptions and experiences of MBSR, and to provide new insights and understanding, and a tentative theory, of how the mindfulness based intervention's work.

Methods

Search strategy. Electronic searching of the following databases: CINAHL, PsychINFO, Scopus, Web of Science, Embase and MEDLINE. Other strategies included manually checking reference lists, contacting authors and searching via a number of relevant websites for ongoing and existing research.

Selection criteria. Studies were included if they met the following criteria: (1) the study was peer-reviewed; (2) the study focused on cancer patients; (3) there were explicit references to the use of qualitative research methods; (4) the study focused on cancer patients' perspectives and experiences of a mindfulness-based intervention; (5) the study was available in English; and, (6) the study was conducted within the previous 10 years, i.e. 2006-2016.

Data collection and analysis. Data was extracted, and methodological quality was primarily assessed by the lead researcher, using the Critical Appraisal Skills Programme (CASP) tool. The studies were further reviewed by two independent reviewers as a quality check and differences in judgement were resolved accordingly.

Results

Eighty-five articles were identified and retrieved from the systematic search. Nine qualitative studies that met the inclusion criteria and passed the screening questions in the quality appraisal were included in the final sample. Critical re-interpretations of the nine selected studies resulted in the emergence of four key themes, (i.e. Perceptual Shift, Connection, Challenge, and Wellbeing and Quality of life), that illuminated cancer patients' perceptions and experiences of the MBI programs.

Reviewers Conclusions

The findings of this review indicated that most participants developed the skills and had the experiences that MBSR was supposed to deliver; patients reported improvements in mood, sleep, fatigue, psychological functioning, psychosocial adjustment, stress management, enhanced coping and wellbeing.

The four themes that emerged from this review provide a possible explanation of how the MBSR program achieved the outcomes reported. The Connection Theme described how an appropriate supportive environment was created that enabled participants to focus on their fears and anxieties, and to do so in a sustained way; this process required discipline and specific skills, such as meditation, which were described by the Challenge Theme. As a result of focusing on negative emotions those emotions 'extinguished', in the same way as they would in Exposure Therapy, and the positive effect of being released from experiencing those negative emotions led participants to reappraise many aspects of their belief systems, which caused significant positive

change in those belief systems, which was described by the Perceptual Shift theme. This profound transformational change led to improvements in the individuals' mental and physical health, which was described by the Psychological Wellbeing and Quality of Life theme, the recognition of which reinforced continued practice of the mindfulness exercises.

Introduction & Background

Upon diagnosis, over half of cancer patients experienced moderate to severe psychological distress and significant difficulty in coping (Mitchell et al., 2011). Decreased quality of life and other psychological problems, e.g. depression, anxiety, stress, insomnia, pain, fatigue and fear of recurrence are commonly experienced by these individuals (Ross et al., 2002). The use of complementary therapies in a supportive role for cancer patients is included in the National Health Service (NHS) guidelines (National Institute for Clinical Excellence, 2004). The guidelines suggest that psychological interventions should form an integral part of the support offered to patients.

One of the most promising Complementary and Alternative Medicine (CAM) therapies, in terms of modifying psychological distress and improving Health Related Quality of Life (HRQoL) among cancer patients, is mindfulness (Ledesma & Kumano, 2009; Carlson & Garland, 2005). Mindfulness Based Interventions (MBIs) have been integrated into several treatment approaches, the foremost of which are, Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT). The aim of this review was to provide an integrated description and interpretation of cancer patients' perceptions and experiences of MBSR, and to provide new insights and understanding, and a tentative theory, of how the mindfulness based intervention's work.

Mindfulness

According to Brown & Ryan (2003) mindfulness, which is based on an ancient Buddhist practice of insight meditation known as Vipassana, is a meta-cognitive skill that involves a mental monitoring of thought process, together with a direct monitoring of attention and awareness of selected aspects of reality, e.g. the external environment. It is a dimension of awareness that is developed through instruction and practice and is cultivated through one being aware and paying attention purposefully and non-judgmentally to one's unfolding experience of thoughts, feelings and bodily sensations on a moment-to-moment basis (Shapiro 2009; Kabat-Zinn 2003). Training involves learning to observe and accept one's internal thoughts, emotions, and physical sensations, as well as external events, as constantly changing phenomena, as opposed to identifying with or reacting reflexively to them. Additionally, an element of intention that is broadly related to kindness, compassion, and relieving or reducing suffering is

also involved. Research has shown that people who have developed these skills may ultimately gain greater freedom to choose how they respond to whatever is happening in each moment, (Shapiro 2009).

Mindfulness Based Stress Reduction (MBSR). In the 1970s Jon Kabat-Zinn and his colleagues at the University of Massachusetts Medical Centre, created MBSR to help patients lead happier lives by decreasing their stress and anxiety levels, as well as other physical and emotional symptoms. The key concepts embedded within MBSR are: a non-judging attitude, patience, beginner's mind, non-striving, acceptance and letting go (see Table 1 for definition of these concepts).

Table 1: Core Concepts of Mindfulness-Based Stress Reduction

Concept	Definition
Beginner's mind	A mind that is willing to see everything as if for the first time, which allows the appreciation of the present moment and the richness of life itself.
Letting go	The putting aside of the tendency to hold onto pleasant mental images and reject unpleasant mental experiences.
Non-judging	The awareness of the constant stream of judging and reacting that is part of our normal experience
Non-striving	Non-doing, the goal of meditation is not to do things for a purpose or a goal
Patience	The understanding and acceptance that things must unfold in their own time
Trust	Developing a basic trust in yourself and your feelings and intuition.

Note: Taken from Full Catastrophe Living, Kabat-Zinn (2005)

A typical MBSR program consists of an 8-week course involving weekly group meetings lasting 2.5 hours, together with a one-day retreat; its goal is to guide individuals towards achieving a greater awareness of their bodies and thoughts. Participants take part in meditation, yoga exercises and group discussions; facilitators are skilled in promoting and exhibiting an attitudinal framework of kindness, curiosity and a willingness to be present-focused. Participants are required to complete daily 45-

minute homework assignments which involve meditation practice and mindful yoga; they are also encouraged to apply mindfulness to situations in everyday life (Kabat-Zinn, 2003).

Mindfulness Based Cognitive Therapy (MBCT). MBCT is derived from both MBSR and Cognitive Behaviour Therapy (CBT), and combines MBSR with traditional Cognitive–Behavioural Therapy techniques. MBCT is based on Kabat-Zinn's (2001) MBSR programme (Segal et al., 2001) and thus it shares the same attitudes, structure and core components of MBSR. Mindfulness interventions have been regarded as part of the cognitive-behavioural tradition. However, MBCT differs significantly from traditional cognitive behaviour therapies in that it does not encourage people to challenge their thoughts, and therapy is not goal directional (Zainal, Booth & Huppert, 2012; Shennan, Payne & Fenlon, 2011). This MBSR version is a manualised 8-week group intervention that is brief, structured and adaptable, and incorporates some cognitive behavioural therapy features to manage physical symptoms that contribute to depressed mood (Ma & Teasdale, 2004). Research findings have suggested that MBCT is at least as good as drugs or counselling and may be a particularly useful tool for addressing depression in medically ill populations (Baer, 2003; Baer & Krietemeyer, 2006). The National Institute for Clinical Excellence has recommended it since 2004 for the prevention of relapse in chronic depression (National Institute for Clinical Excellence (NICE), 2004, 2009).

Mindfulness in oncology. Specca et al., (2000) modified the MBSR program to improve its suitability for use in the cancer population, this precipitated a marked increase in interest in both the clinical aspects of mindfulness and the research into its effectiveness in Oncology (Shennan et al., 2011).

Research has identified that MBIs enhance Post Traumatic Growth (PTG) and are associated with increased spirituality. In a non-randomised comparison study, Garland et al., (2007) compared MBSR and a Healing Art (HA) program on measures of Post-Traumatic Growth (PTG), spirituality, stress and mood disturbance in cancer patients. Increased PTG was associated with increased spirituality in the MBSR group and improvements in stress and mood disturbance were also found to be greater in the MBSR group. Furthermore, a comprehensive review of the literature (Ott, 2006), systematic reviews (Smith et al., 2005; Musial et al., 2011; Shennan 2011; Piet, 2012; Cranmer, 2012) and meta-analysis studies (Matchim, 2011; Zainal, 2012; Lesdema,

2009) have documented MBI's particular effectiveness in both reducing psychological distress and improving psychosocial adjustment to cancer diagnosis.

The Smith et al., (2005) systematic review of the literature on MBI in oncology documented MBI's potential as a clinically valuable intervention for cancer patients in terms of improving sleep quality, reducing stress and improving mood. Shennan, Payne & Fenlon's (2011) systematic review of mindfulness-based interventions (MBSR, MBCT, and three other MBIs) in adult oncology care suggested that MBI's had a positive impact, e.g. sexual difficulties were reduced, and self-perceived well-being was increased, and they also positively impacted physiological markers of stress and immune function; these findings were in addition to the reduced anxiety and depression. It was concluded that MBIs had significant promise in the overall care of adults with cancer.

Collectively, the above studies suggest that MBIs have been effective in improving a wide range of symptoms associated with a cancer diagnosis. The reported benefits of the MBIs in this context include: stress reduction; improved immune function; reduced mood-disorders (e.g. anxiety and depression); and, reductions in sleep disturbances, cancer related fatigue and low energy states. Improved psychological functioning and reductions in psychological distress, in relation to the cancer diagnosis, have also been reported outcomes of MBIs with patients displaying more effective coping capabilities, less fear of disease recurrence, fewer sexual difficulties and improved physical functioning, wellbeing and perceived HRQoL.

Why a synthesis of qualitative work is needed? Although in recent years there has been qualitative research published on mindfulness-based interventions, there is as yet no cumulative body of knowledge about or theoretical understanding of mindfulness. According to Sandelowski, Docherty & Emden (1997) "individual qualitative studies risk being lost as disparate isolated islands of knowledge without some attempt to sum them up" (p.367). The problem that was addressed in the current meta-synthesis was the lack of any overarching explanation of the findings from qualitative studies that have examined experiences and outcomes of participants who have used MBSR or MBCT in an oncology setting. Sandelowski et al., argued that the aim of qualitative meta-synthesis is to account for all important similarities and differences in language, concepts, images and other ideas around a target experience.

The aim of this meta-synthesis was to describe and analyse the qualitative studies which examined cancer patients' perceptions and experiences of MBSR and

MBCT. It has the potential to expand findings of existing qualitative studies on these MBI's in ways that may be useful for improved clinical practice in oncology.

Method

Meta-synthesis synthesises qualitative findings across studies to produce new integrated, descriptive and explanatory interpretations and perspectives of an event, phenomenon or experience (Fingfeld, 2003; Sandelowski, 2007). Although Meta-synthesis is guided by different approaches and techniques, there are some common characteristics, most notably, teamwork among a group of researchers, within the same field of interest, and interpretative analyses to synthesise the evidence, based on a systematic search of the literature (Sandelowski, 2007).

The aim of the current study, which is a meta-synthesis guided by the work and writings of Sandelowski and Barroso (2007) (Table 2), was to provide an integrated description and interpretation of cancer patients' perceptions and experiences of MBSR, as well offering new insights and understanding, and a tentative theory, of how the MBSR/MBCT interventions work.

Metasynthesis process. The process involved collating relevant data (qualitative studies), appraising the studies and finally a meta-summary and meta-synthesis; each of these steps is described below.

Formulation of a research question. For qualitative meta-synthesis a broad research question is important to fully capture work conducted relating to the phenomenon of interest (Fingfeld, 2003). With this in mind the research question for the current study was: 'What are cancer patients' perceptions and experiences of MBSR?'

Inclusion and exclusion criteria. Studies were eligible for inclusion if they met the following criteria: (1) the study was peer-reviewed; (2) the study focused on cancer patients; (3) there were explicit references to the use of qualitative research methods; (4) the study focused on cancer patients' perspectives and experiences of a mindfulness-based intervention; (5) the study was available in English; and, (6) the study was conducted over the last 10 years (2006-2016).

TABLE 2 Qualitative Meta-Synthesis

(Sandelowski & Barroso, 2002, 2007)

1. **Formulate the review question**
2. **Conduct a systematic literature search**
3. **Screen and select appropriate research articles**
4. **Extract the results**
5. **Analyse and synthesise qualitative findings**
6. **Maintain quality control**
7. **Present the findings**

Search strategy. Prior to commencing the review, the databases of the National Institute for Health Research Centre for Research and Dissemination (NIHR) and PROSPERO were searched to identify whether any similar systematic reviews were currently being conducted (none were found). Relevant published qualitative research studies were identified using the following electronic databases: CINAHL, PsychINFO, Scopus, Web of Science, Embase and MEDLINE. The following search terms were used: (cancer* OR neoplas* OR tumor* OR tumour*) AND (experience* OR perception* OR thought* OR feeling*) AND (mindfulness OR "mindfulness-based cognitive therapy" OR "mindfulness based cognitive therapy" OR MBCT OR "mindfulness-based stress reduction" OR "mindfulness based stress reduction" OR MBSR) AND ("qualitative" OR "qualitative research"). See Tables 3 and 4 for further detail regarding identification of studies from electronic databases. Studies identified in each database were exported to and combined in the reference software package Endnote and duplicates removed.

Table 3: Electronic databases searched (August 2013)

Database	Search dates	Total hits
PsychoInfo	1999-	8
CINHAL	1999-	28
Scopus	2007-	15
Embase	1980-	23
Medline	2005-	8
Web of Science	2005-	3
TOTAL		85

Table 4: Study Selection Process

Study selection process	**Number of Articles**
Total references retrieved	85
Duplicates removed	52
Rejected at title	14
Total abstracts screened	19
Rejected at abstract	10
Total full papers screened	9
Rejected full papers	0
Total papers included	9

Studies were excluded if they: (1) examined non-patient perspectives only (e.g., that of healthcare professionals); (2) used quantitative research methods only; (3) were theoretical or methodological articles or (4) were dissertations or book chapters.
As the purpose of this study was to investigate patient experience of the 8-week course of MBSR or MBCT, studies based on meditation alone were excluded. Papers that referenced the MBSR/MBCT approach but employed interventions that differed from the standard program, e.g. in terms of session length or duration of course, were only included if there was a clinical justification for deviating from the standard MBSR package. For example, Chadwick, Newell & Skinner (2008) provided a clinical justification for adopting a non-standard MBSR approach, i.e. participants had been too ill to cope with standard length exercises and this study was therefore included. Studies that did not provide any clinical justification were excluded, e.g. the Ando et al., (2011) study was excluded.

Overview of identified literature included in the meta-synthesis. Nine papers met the inclusion criteria and passed the screening questions. A brief summary of the key features of the identified literature (Table 5) details: the aim of the study; the theoretical and methodological orientation; the type of finding; and, details about the samples in these studies. There was a total of 214 participants in the 9 studies; all were cancer patients and they were predominantly female, i.e. 208 from a sample size of 214. The age-range for the full sample could not be calculated because Hoffman et al., (2012) and Schellekens et al., (2016) did not report the age range of their samples, (n=92 and n=40 respectively) and L'Estrange (2016) did not provide the age of their 1 male participant; the age range for the remaining participants was 21-80 (n=81). The mean age for the full sample could not be calculated because three studies, i.e. Chadwick et al., (2008), Eyles et al., (2015) and L'Estrange (2016) did not report the mean age of their participants (n=5, n=19 and n=10, respectively), the mean age for the remaining participants was 51.6 years (n=180).

Participants' diagnosis was predominantly breast cancer, i.e. 200 of 214; the other cancer diagnoses were terminal (type unspecified) n=5, Prostate n=2, Ovarian n=1, Malignant Melanoma n=1, Lymphatic n=1 and Multiple n=4. The intervention adopted by the studies was mainly MBSR (n=204), one study (L'Estrange et al., 2016) used MBCT Intervention (n = 10). Researchers collected qualitative data using a range of methods that included questionnaires, semi-structured interviews and focus groups; qualitative data in the studies were analysed using a variety of qualitative methods, i.e.

content and thematic analysis, IPA, grounded theory analysis and a framework for analysing focus group data developed by Richard Krueger (1998). The studies included within the review were conducted in six different countries, namely the UK (Dobkin, 2008; Chadwick et al; Hoffman et al., 2012; Eyles et al., 2015), Canada (Mackenzie et al., 2006), Sweden (Kvillemo et al., 2011), Netherlands (Schellekens et al), Ireland (L'Estrange et al., 2016) and the USA (Weitz et al., 2012). Researchers were interested in facets of experience associated with taking part in MBI's and in developing new theories from the analysis of participants' accounts of their experiences. They identified a range of themes that covered a number of different aspects of the participants' perceptions and experiences of MBI, most of which were positive and ranged from beneficial changes in perceptions of self and the illness, to practical skills for both managing negative emotions and pain and improving general well-being.

TABLE 5: Summary Details of Papers Analysed

Source Paper (n=9)	Cancer Type	Intervention	Age & Gender	I. Method ii. Data Analysis
Chadwick et al 2008. (UK)	Terminal	Simplified MBSR (1 hr/week: 2x10 minute breathing sessions &reflective discussions)	(N=5) 2 females, 2 males, 1 unknown. Age Range 54-77. Average not given	i. Individual interviews ii.IPA
Dobkin (2008) (UK)	Breast	MBSR	(N=13) All female. Age Range 37-70; average 54	i.Focus groups: 6 questions discussed for 15 minutes, transcribed verbatim ii.Krugers framework for analysing focus group data
Eyles et al., (2015)	Metastatic Breast (MBC)	MBSR	(N=19) All female. Age range 37-65; Average not given	i.mixed methods semi-structured interviews, focus groups recorded and transcribed verbatim + questionnaires. ii.Thematic analysis using constant comparison technique.
Hoffman et al., (2012) UK Study	Breast	MBSR	(N=92) All female. Age range not given, Average age 49	i.group's short proforma ii.content and thematic analysis
Kvillemo et al., (2011)	Breast (n=17) & Lymphatic (n=1)	Modified MBSR (all day retreat excluded)	(N=18) All females. Age range 31-65, average 54	i.Telephone interviews ii. thematic analysis

TABLE 5: Continued

Source Paper (n=9)	Cancer Type	Intervention	Age & Gender	i.Method ii.Data Analysis
L'Estrange (2016)	Breast (n=7) & rare form (n=3)	Mindfulness Based Intervention	(N=10) 9 females age range 33-63, no average, 1 male unknown age.	i.Semi structured interviews ii.descriptive interpretive approach
Mackenzie et al., (2006)	Breast (n=4), Prostate (n=2), ovarian (n=1), Malignant melanoma (n=1) & multiple (n=1)	MBSR weekly drop in	(N=9) 7 females. Age range 43-77; average 60.8	i.semi structured interviews and focus group ii.Grounded theory analysis QSR N6 software to identify themes.
Schellekens et al., (2016)	Breast	MBSR 8-weekly 2.5 hr sessions. 6-hr silent day between sessions 6 and 7.	(N=40) Gender not given. All over 18 years old, average age 52.3	i.focus groups and individual interviews, ii.Constant comparative method to develop grounded theory.
Weitz et al., (2012) USA study	Breast	MBSR	(N=8) All female. Age range 21-80; average age 58.5	i.interviews ii.IPA and modification of the Van Kaam method of Phenomenological Methodology

TABLE 5: Continued

Source Paper n=9	Aim	Findings
Chadwick et al (2008) (UK)	To investigate the experiences & benefits of a mindfulness training program for a group of terminal cancer patients	Participants report mindfulness beneficial across emotional, physical, spiritual and social elements.
Dobkin (2008) (UK)	To investigate patients' views of the intervention itself, and mindfulness application to their lives	Themes identified: acceptance, regaining & sustaining mindful control, and taking responsibility forwhat could change & having a spirit of openness and connectedness.
Eyles et al., (2015)	To investigate the acceptability and feasibility of providing MBSR for women with MBC and of introducing MBSR into an NHS setting	Three main themes emerged: Barriers to participation and recruitment, Challenges, Acceptability/benefits "an additional band of inner strength" and acceptability/challenges.
Hoffman et al., (2012) (UK)	To investigate the acceptability of MBSR in women with breast cancer diagnosis	Following MBSR training, Participants report they have become more mindful
Kvillemo et al., (2011)	To examine the effects and experiences of mindfulness as described by cancer patients following their completion of an eight week program	The study supports the use of mindfulness programs to reduce stress related complaints amongst some patients. Also a positive impact upon sleep quality, pain & well-being
L'Estrange (2016)	To explore shifts in self relating self-compassion in the context of MBI	Enhanced awareness reduced engagement with ruminative thoughts and an increased sense of choice and agency
Mackenzie et al., (2006)	To investigate the impact of mindfulness model on patients and how MBSR influences their lives and ability to manage their illnesses	Themes interpreted to fit mindfulness of re-perceiving. Main themes: opening to change, self-control, shared experience, personal growth, spirituality.
Schellekens et al., (2016)	To further explore how women with breast cancer experience the possible benefits and impediments of being with fellow patients the context of an MBSR training	Mixed findings: benefits from peer support when embedded in mindfulness based stress reduction.
Weitz et al., (2012) USA study	To investigate the experience and significance of mindfulness-based stress reduction for survivors of breast cancer	MBSR found to be a valuable tool for recovery after breast cancer. This is found to enhance self-care techniques

Critical appraisal. Prior to conducting the synthesis each paper was assessed using criteria based on the critical appraisal skills programme (CASP) as used in other meta-syntheses (Malpass et al., 2009). The CASP proforma is provided in appendix (A).

To quickly eliminate inappropriate papers from the appraisal and synthesis processes, two screening questions were employed: 1) 'Was there a clear statement of the aims?' and 2) 'Is this study qualitative research?' Individual appraisal of each paper was conducted, which involved 10 questions each requiring a response of 'yes', 'no' or 'unclear' - a 'yes' response scored 1 and a 'no' or 'unclear' response scored 0. Reviewers (see below) agreed that a paper would only be included in the meta-synthesis if it obtained a score of at least 6.

Although there were some weaknesses, i.e. the transparency of methodology employed and extent of comment on reflexivity, all nine papers achieved a score of 8 or above (see Table 6), i.e. the quality of the papers was good, and they were therefore all included in the meta-synthesis. Data was extracted from the papers using a summary sheet (Appendix B) and a comparative appraisal across the nine studies was carried out. Key features of the nine studies are presented in table 5.

Meta-summary and meta-synthesis. Appraising quality was essentially the first phase of repeated readings of the studies leading to identification of recurring themes across studies and this stage helped to identify how the studies were related. The first iteration of key themes was derived from both the verbatim text of the participants in the studies, and from the themes identified by the authors of the studies. These themes are representative of first and second order constructs respectively. Translating the studies into one another, for example, translating one study's findings into another using metaphors and concepts that could be applied to both, entailed examining the key themes in relation to others in the selected study and across the nine studies, whilst utilising external literature to facilitate interpretation of the emerging findings, i.e. analogous to the method of constant comparison used in qualitative data analysis. The translation of key themes from one study to another was idiomatic rather than word for word translation. Finally, the contents and meanings were synthesised, clustered into a new structure of meanings and given a name, i.e. new themes were created. The next step described each new theme in text representing and mediating a whole and an understanding that went beyond and behind (Fingfeld, 2003), but remained faithful to the studies.

The process of appraising quality, analysis and synthesis was primarily led by one member of the research team (SE) and findings were fed back to the other two team members, both of whom had read each of the nine studies. Differences between the team members emerged, particularly with regard to the utility of appraising the quality of studies, the degree of importance attributed to particular key themes and the identification of core concepts. The three reviewers had discussions to resolve differences and the final composite analysis and synthesis was agreed by consensus.

Table 6: The Screening Questions

SCREENING QUESTIONS.	STUDY NUMBER								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Was there a clear statement of research aims	Y	Y	Y	Y	Y	Y	Y	Y	Y
Is this study qualitative research?	Y	Y	Y	Y	Y	Y	Y	Y	Y
Was the research design appropriate to address the aims of the research?	Y	Y	Y	Y	Y	Y	Y	Y	Y
Was the recruitment strategy appropriate to the aims of the research?	Y	Y	Y	Y	Y	Y	Y	Y	Y
Were the data collected in a way that addressed the research issue?	Y	Y	Y	Y	Y	Y	Y	Y	Y
Has the relationship between researcher and participants been adequately considered	N	Y	Y	Y	N	N	Y	Y	N
Have ethical issues been taken into consideration?	Y	Y	Y	Y	Y	Y	Y	Y	Y
Was the data analysis sufficiently rigorous?	U	Y	Y	Y	Y	Y	Y	Y	Y
Is there a clear statement of findings?	Y	Y	Y	Y	Y	Y	Y	Y	Y
How valuable is the research?	Y	Y	Y	Y	Y	Y	Y	Y	Y
OVERALL QUALITY RATING	**8**	**10**	**10**	**10**	**9**	**9**	**10**	**10**	**9**

KEY: STUDY NUMBER

1.Dobkin 2008. 2.Chadwick et al.2008 3.Kvillemo et al.2011 4.Hoffman et al.2012 5.Weitz et al.2012

6. Eyles et al.2015 7.Lestrange et al.2016 8. Schellekens et al.2016 9.Mackenzie et al.2006

Table 7: Emerging themes and associated studies

Theme	Study
Challenge	Chadwick et al., (2008)
	Eyles et al., (2015)
	Hoffman et al., (2012)
	Kvillemo et al., (2011)
	L'Estrange et al., (2016)
	Schellekens et al., (2016)
Connection	Chadwick et al., (2008)
	Dobkin (2008)
	Hoffman et al., (2011)
	Kvillemo et al., (2011)
	L'Estrange et al., (2016)
	Mackenzie *et al.,* (2006)
	Schellekens et al., (2016)
	Weitz et al., (2012)
Perceptual Shift	Chadwick et al., (2008)
	Dobkin (2008)
	Eyles et al., (2015)
	Hoffman et al., (2012)
	Kvillemo et al., (2011)
	L'Estrange *et al.,* (2016)
	Mackenzie et al., (2006)
	Scheellekens *et al.,* (2016)
	Weitz et al., (2012)
Psychological Wellbeing And QoL	Chadwick et al., (2008)
	Dobkin (2008)
	Eyles et al., (2015)
	Hoffman *et al.,* (2012)
	Kvillemo *et al.,* (2011)
	L'Estrange et al., (2016)
	Mackenzie et al., (2006)
	Scheellekens et al., (2016)

Synthesis of Findings

The findings of the nine identified papers were synthesised with the aim of examining and integrating contemporary qualitative research on patients' perceptions and experiences of MBSR and MBCT as a therapy for cancer patients. Four conceptual themes emerge from the analysis of the data: (1) Perceptual Shift; (2) Connection; (3) Challenge, and (4) Psychological Wellbeing and Quality of Life. As can be seen in Table 7, studies tended to contribute to more than one (and sometimes all) conceptual theme(s); each of the nine included studies contributed to a minimum of two themes.

Conceptual Theme 1: Perceptual Shift

"There was a richness and depth to my perception" (Weitz et al., 2012, p.26)

Throughout the identified literature, it was argued that the Mindfulness Based Interventions (MBIs) resulted in participant changes indicative of a fundamental shift in perspective (Mackenzie et al., 2006; Dobkin, 2008; Chadwick et al., 2008; Kvillemo et al., 2011; Hoffman et al., 2012; Weitz et al., 2012; Eyles et al., 2015; Schellekens et al., 2015; L'Estrange et al., 2016.) Typically, participants' accounts were indicative of perceptions of life as newly seen or seen through different eyes following the program. Weitz et al., (2012) discussed this in terms of 'cognitive reconceptualisation' and argued that MBI concepts, such as being present and loving kindness, changed participants' view of the world and helped them to re-define their perspectives about themselves, their values and their future. Some papers went over and above this perspective, for example, Mackenzie et al., (2006) and L'Estrange et al., (2016) argued that underlying this process was the beginning of a shift in orientation that began a growth process that ultimately led to a transformation. Several authors positioned the 'perceptual shift' in the context of an enhanced awareness (Dobkin, 2008; Hoffman et al., 2012; Kvillemo et al., 2011; L'Estrange et al., 2016; Schellekens et al., 2015); some researchers suggested that mindfulness techniques enhanced participants' awareness of moment to moment experiences which resulted in them paying increased attention to experiences in the present moment (Kvillemo et al., 2011; Hoffman et al., 2012).

Frequently emphasised in participants' accounts and researchers' reporting was the idea that being mindful enabled individuals to be present to life's beauty and to manage life's challenges differently. Participants were able to weave awareness of the present moment into their everyday lives; some individuals described the role of

mindfulness in terms of being pervasive. Participants endeavoured to be watchful of how events and circumstances influenced their lives, and this enhanced awareness resulted in a greater appreciation of life's beauty and its quality (Hoffman et al., 2012, p. 224; Dobkin, 2008, p. 13).

In all papers, individuals in MBI programs experienced, 'increased clarity in the perception of life' (Hoffman, et al., 2012, p.224). Participants expressed experiencing revelations or wholly new sensations; this is evident in the following examples:

> *"… but some of the exercises were so amazing. We were to do them slowly. We drank tea and ate a raisin and chewed it properly. We did it there and it was like "wow" It was a real "aha" thing" (Kvillemo et al., 2011, p27).*
>
> *"Simply noticing beauty in everyday life is a treasure" (Hoffman et al., 2012, p. 224),*
>
> *"There was richness and a depth to my perception. I didn't take anything for granted" (Weitz et al., 2012, p. 26)*

Shift in relation to 'self' and others. Seven of the identified papers suggested an enhanced awareness and re-focusing of self, i.e. it appeared that MBIs made a difference in the way participants related to both themselves and others. As a participant in Hoffman's (2012) MBI group asserted:

> *"Its changed my outlook on my life, my relationship to other people and, most importantly, my relationship to myself… that's the one person I have to deal with every day."*

MBI techniques led participants on a journey to embrace and accept things as they were, and subsequently those individuals regained a sense of self which had been lost following the cancer diagnosis. As a participant in the Weitz et al., (2012) study said:

> *"The MBSR really helped in getting me get back in touch with whom I am and what I'm all about - that I'm not the breast cancer survivor" (Weitz et al., 2012, p.28).*

It appeared that MBI's served to change participants' perspectives on living with cancer (Mackenzie et al., 2006; Dobkin, 2008; Chadwick et al., 2008; Schellekens et al., 2015). They saw their illness in a different light and they came to relate differently and more positively to their cancer experience, as illustrated by the comment:

> *"I don't dwell on it so much you know…I'm happier in myself and more (pause) accepting I think (pause). He (pause) he taught us to look at our illness in a different*

> *way…I think (pause) think that is the main thing really he taught us, to look about the illness differently and it made us more able to cope and rise above it…" (Chadwick, Newell & Skinner, 2008, p.138)*

The focus on 'self' added a new perspective to participants' lives which enhanced positive feelings about themselves. MBSR core practices, such as non-judgmental awareness and loving kindness meditations, made participants aware of how judgmental they were of themselves and others, and as a consequence, a kindlier attitudinal shift occurred.

Participant accounts in the identified papers described shifts in self-relating, in terms of being kinder and less hard towards the self and suggested increased self-kindness and reduced self-judgement (Mackenzie et al., 2006; Dobkin, 2008; Kvillemo et al., 2011; Hoffman et al., 2012; Weitz et al., 2012; Eyles et al., 2015; L'Estrange et al., 2016). Examples include:

> *"… the non-judgmental 'permission' concept has made space from the critical part of my mind which has often overwhelmed me in the past" (Hoffman p.225), and "… become kinder to yourself, and maybe also kinder toward other" (Kvillemo, p.27).*

This resulted in participants' ability to take time and create space for themselves. Since, following their participation in the MBI, individuals took more time to consider the self before committing to others in order to avoid overextending themselves. L'Estrange (2016) described this attitudinal shift toward the self as relating to the self with reduced pressure, increased kindness and self-acceptance. This self-compassion was explained as being reinforced cognitively and emotionally by, "*a shift in the way that* {*you*} *think about giving the self time* (Heather) and, '*letting go of feeling guilty'* (Gina)."

Conceptual Theme 2: Connection

Frequently emphasised in participant accounts and researchers' reporting was participants' feelings of connection, or re-connection, as a result of the program. Cancer diagnosis often results in feelings of isolation and disconnectedness (Mackenzie, Carlson, Munoz, & Speca, 2007) and many MBI participants cited expanded connectedness and increased awareness of being connected to others and wishing to engage with others in a meaningful way (Dobkin, 2008). Moreover, they reported a new and enhanced 'spirituality', which included dimensions such as making meaning of life, faith, purpose, and connection with others and a higher power. Participants across

studies emphasised connecting with others whilst taking part in the group activities and they talked of connection in terms of their connection with an inner self and a 'mind-body' connection, (Mackenzie et al., 2006; Dobkin, 2008; Chadwick et al., 2008; Kvillemo et al., 2011; Hoffman et al., 2012; Weitz et al., 2012; Schellekens et al., 2015; L'Estrange et al., 2016).

Connecting with others in a social group. Participants felt a sense of, "fellowship, camaraderie and connection" (Mackenzie et al., 2007, p.64), and there was a sense of a collective whole, a shared bond that transcended individual suffering, as illustrated by the comment: "We are all sisters. I consider us sisters" (Dobkin, 2008, p. 13).

Individuals felt connected to the group often because of shared experiences; the sense of stigma surrounding the illness experience was reduced in the group context, e.g. patients described the group as a place of support through shared identity:

> *"you come for not only learning how to connect with yourself, but you're also connecting with other people who understand the pain. Not necessarily just the physical but the mental pain of what cancer is. Is about life, right in the circle, right in that room" (Mackenzie et al., 2006, p.64).*

> *"It's being amongst people who are, have a life-shortening illness and you don't therefore feel odd. You are one, you are normal there and people-you don't have to excuse anything, you are accepted for what you are and they seem to see past the problems and see me as me!" (Chadwick et al., 2008, p.141).*

Schellekens et al., (2015) commented that participants recognised themselves in each other and that this served to lessen the need to explain things that people without cancer might not understand (p 1816). In other respects, several other researchers suggested that MBI provided community, support, solidarity and trust; that it helped to meet participants' needs for safety and their understanding that they were not alone in their journey, (Mackenzie et al., 2006; Schellekens et al., 2015; Hoffman et al., 2012).

Inner self and 'mind-body' connection (connecting mind and body). An enhanced awareness of mind and body enabled participants to connect better with themselves and gain access to the central, calm and peaceful place within (Mackenzie et al., 2006; Hoffman et al., 2012; Weitz et al., 2012; L'Estrange et al., 2016); illustrative comments include:

> *"You know I sit down and I - it's just me and the meditation, it's very soothing. It enhances what's around you, you know the sound and tuning into your bodily sensations" (Weitz et al., 2012, p.96).*

> *"I feel more at peace and at home with myself and my body than I have in a long time" (Hoffman et al., 2012, p.224).*

Participants cultivated relationships within themselves in which they built and nurtured their inner lives (Mackenzie et al., 2006, p. 65).

Connection and spirituality. Although MBIs had a secular stance, a growing spirituality might have been an inevitable outcome of the program, (Mackenzie et al., 2006; Chadwick et al., 2008; Hoffman et al., 2012; Weitz et al., 2012; L'Estrange et al., 2016). For example, Mackenzie (2006) argued that core practices within the program supported spiritual growth, and that participants developed 'a growing spirituality' and an ability to identify and appreciate spiritual resources and tools that were not considered prior to the program. Meditation, for some had started to blend in with other spiritual and religious practices, particularly prayer, i.e. mindfulness practice promoted an awareness of the intricate interconnections between self and other individuals, which predisposed participants to a spiritual experience. Furthermore, for some individuals this extended to an interconnection with a 'higher power', for example, one participant, Sandra (Weiz, 2012) commented, "its also a way for me to talk to my higher power" (p 28); further illustrative comments included:

> *"…well I'd like to emphasize just that whole business of spiritual strength that can be gotton through mindfulness." (Weitz et al., p.28).*

> *"Doing meditation brought me more into the spiritual. A lot of times I'll do meditation and then I'll do a prayer after that or before, one of the two. I kind of link the two together. The mindfulness and meditation brought me back more into the spiritual part of it." (Mackenzie et al., 2007, p.65)*

Conceptual Theme 3: Challenge

Six papers in the synthesis incorporated aspects of the MBI program that participants found confronting (Chadwick et al., 2008; Kvillemo et al., 2011; Hoffman et al., 2012; Eyles et al., 2015; Schellekens et al., 2015; L'Estrange et al., 2016). For example, the formal practice part of the MBSR program raised various challenges for a number of participants. Several papers mentioned an intensified emotional vulnerability amongst participants (Kvillemo et al., 2011; Schellekens et al., 2015; L'Estrange et al.,

2016) and a number of participants described this, for example. one participant (Cara) asserted that, "it stripped me to the core." (L'Estrange, 2016, p.739), while another described powerful emotions surfacing and being released during mindfulness practice sessions:

> *"It was hard doing the exercises on our own at home… I also thought that the techniques were somewhat too powerful in one way, if you don't feel emotionally stable…I felt like I needed to talk to someone who had the right competence, not just talk to a friend" (Kvillemo & Branstrom, 2011, p. 28).*

One paper reported that experiencing the stories of the participants in the group weighed heavily upon the shoulders of some,

> *"Well, I thought it was a little scary…my last chemo was not that long ago and I was scared of what would come and then you hear these stories. I was thinking "oh my goodness, this can happen to me too" (Schellekens et al., 2015).*

Researchers also appeared to locate 'challenge' within the context of motivation, preferences, intention, engagement with, and misunderstanding of, the MBI program (Chadwick et al., 2008; Kvillemo et al., 2011; Hoffman et al., 2012; Eyles et al., 2015). There was tension in evidence when participants showed frustration and appeared to misunderstand aspects of the mindfulness practice; for example, some individuals did not seem to be aware that in contrast to eliminating or controlling thoughts, mindfulness is a technique for observing them with an attitude of kindly, curious detachment (Kabat-Zinn, 2005). This lack of understanding is illustrated by the comment of one participant who explained how he regarded his thoughts as, "logical…they're thoughts I need to have" (Chadwick, 2008, p.140) and also illustrated by another participant, who had difficulty engaging with the mindful eating exercise, and commented, "…oh and the silent eating – I could never get on with the eating."

A number of participants across the papers reported perceiving the course schedule as being too structured and prescriptive, while others found difficulties completing the homework exercises. Complaints included: difficulty concentrating, poor motivation, remembering to do it, falling asleep while practicing, wanting to do something else while practicing, not wanting to do the practice and finding the practice period of 45 minutes, too long (Chadwick et al., 2008; Kvillemo et al., 2011; Hoffman et al., 2012; Eyles et al., 2015). Illustrative comments include:

"... I want to find the time for it, but it is a more difficult thing when you have 3 children" (Kvillemo & Branstrom, 2011, p. 29);

"My problem is remembering to do it sometimes causes you know, if my wife says 'Maybe try the mindfulness, it would help' but you know so, err, err, I said yeah but at the time you don't feel like doing it.' (Phil, p141 Chadwick et al., 2008)

In addition, some participants had trouble performing some of the physical exercises because of body stiffness or back pain, as illustrated by the comments:

sitting meditation was something that I really struggled with - and sometimes still do - a combination of "monkey mind" and physical discomfort" (Hoffman p. 224)

"What was difficult for me was to find a good position because I am so very rigid in my body. I could not sit down." (Kvillemo. & Branstrom, 2011, p. 27)

Conceptual Theme 4: Psychological Wellbeing and Quality of Life.

"...general improvement in my level of satisfaction with the life I'm leading" (Mackenzie et al., 2006 p.64)

All researchers reported improved psychological wellbeing and quality of life (QoL) to be an outcome of participation in MBI programs (Mackenzie et al., 2006; Dobkin, 2008; Chadwick et al., 2008; Kvillemo et al., 2011; Hoffman et al., 2012; Weitz et al., 2012; Eyles et al., 2015; Schellekens et al., 2015; L'Estrange et al., 2016). For example, Weitz et al., (2012) discussed this in terms of how MBI enhanced the life experience and quality of life for cancer survivors and they concluded that participation in the program led to decreased fear of disease recurrence and enhanced enjoyment of life (p. 28). Other papers, for example Kvillemo et al., 2011 and Eyles et al., 2015 detailed how MBI improved psychological health and wellbeing in terms of better management of distress and its positive impact on sleep quality, pain, fatigue and general wellbeing. Chadwick (2008) emphasised that participants had understood that benefits were about quality of life, rather than altering the course of the illness (Chadwick p139).

The following improvements, experienced by participants during the MBI's, were reported in the identified literature: 1. increased energy levels; 2. self-reported decrease in physical complaints and use of medications; 3. Improved ability to cope with their illness; 4. Increased proactivity and ability to take time for themselves; 5. improved relationships and communication with others; 6. Improved ability to manage

stressful situations and negative emotions i.e. anxiety and depression; and, lastly 7. greater enjoyment of the normal things in life.

The idea that the program provided a toolbox of skills that individuals could use to improve their lives, i.e. to combat the physical effects of illness, to improve psychological well-being and to manage life's challenges differently, appeared frequently in both the accounts of participants and the researchers' reports. This is illustrated by comments such as:

> *"when I see some, feel some signs, I just stop and say, well do something for it" (Dobkin, 2008, p.12).*
>
> *"… I now feel that I have a way of understanding and dealing with stress which is available to me every moment of my life" (Hoffman et al., 2012, p.224).*
>
> *"There are times that I am having trouble falling asleep or you know all the demons start going round me and I'll focus on my breath" (Weitz et al., 2012, p.27).*
>
> *"I can also notice that I am more alert...", and, "I get spasms…when everything just goes rigid and I try to breathe properly (pause) maybe it helped that way". (Chadwick et al., 2008, p. 139)*

Participants used MBI techniques, such as the breathing exercises, to re-establish a sense of calm and control. This was identified across all studies in the identified literature. Individuals found that focusing attention on the present moment was effective in the management of fear, including: fear of the future; the reduction of worrying doubts; negative self-talk; and, their natural inclination to ruminate on what might have been and what might be in the future. Mackenzie et al., (2006) argued that the practice of mindfulness provided a means by which individuals monitored and controlled their own arousal and were able to face and evaluate their own problems with greater equilibrium.

Participants thought of the benefits of MBSR pragmatically and detailed specific and tangible benefits, as illustrated by the comments:

> *"I am much more confident and self-assured than I was in the beginning. With this confidence I have the courage of my convictions to change certain aspects of my life which I wouldn't have done before…I am very much aware of what is good for me (mentally and physically) and will actively change things" (Hoffman et al., 2012, p. 224).*

Discussion

The primary goal of this meta-synthesis was to describe and analyse cancer patients' perceptions and experiences following completion of Mindfulness Based Intervention's (MBI's). Critical re-interpretations of nine selected studies were completed from which four key themes emerged, i.e. Perceptual Shift, Connection, Challenge and Psychological Wellbeing and Quality of Life. In line with the theoretical foundation of MBSR the results of this study indicate that most participants developed the skills and had the experiences that MBSR was designed to deliver (Kabat-Zinn, 2005). Results of this meta-synthesis are consistent with systematic review of MBSR in oncology, which have documented its effectiveness for improving mood, sleep, fatigue, psychological functioning, psychosocial adjustment, stress management, enhanced coping and well-being in cancer patients (Shennan, Payne & Fenlon, 2011).

The findings of this study indicate that mindfulness practice increased participants' capacity to be objective when examining personal experiences, which in turn produced a shift in perspective. One theory explaining how this shift occurs has been proposed by Shapiro, Carlson, Astin & Freedman (2006) who focused on the interaction between what they identified as the cornerstones of mindfulness, i.e. Intention, Attention and Attitude (IAA). Intention refers to the personal reason why one is practicing mindfulness, attention refers to the purposeful focus of attention on one's moment to moment experiences (internal and external), and attitude refers to the requisite attitude of curiosity, non-striving and acceptance. Shapiro and colleagues labelled the shift in perspective as 're-perceiving', which they described as a change that allowed one to be deeply connected with one's experience without identifying with it, or overlaying it with unconscious commentary (Shapiro et al., 2006).

That participants experienced this shift in perspective and readily embraced living non-judgmentally in the present is unsurprising in view of how their disease predisposed them to anxious thoughts about future illnesses/treatments and past lifestyle decisions. The clarity, calmness and peace of mind associated with mindfulness allowed potentially anxiety-producing thoughts to be confronted without the escalating panic and fear that had previously been generated by those thoughts; participants had successfully disentangled themselves from reflexive behaviours and acquired effective emotion regulation (Mullens, McCaul, Erickson & Sandgren, 2004). Voluntary self-regulation of physiological and mental states was an important development because it

led to improved well-being and QoL, which implies that MBIs can be conceptualised as a toolbox for improving well-being and QoL.

An important feature of cancer is that it often creates a disconnect between mind, body and self with distressing consequences for the patient, i.e. cancer disrupts what Baron (1985) described as the unselfconscious unity of body and self that most people take for granted. This meta-synthesis found that MBI programs were beneficial in helping participants combat this unpleasant state, i.e. they created an enhanced awareness of mind, body and self, which promoted a reconnection between these entities. Results of this study suggest that MBIs can change patients' perceptions of their illness in such a way that the disease loses its power to define the individual, i.e. through mindfulness practice cancer becomes an event, not a defining characteristic (Coker, 1999). Participants in the present study appeared to have experienced this re-connecting; furthermore, committing to mindfulness resulted in feelings of enhanced spirituality. This finding has been acknowledged elsewhere: Garland, Carson, Cook, Lansdell & Speca (2007) reported that MBSR enhanced spirituality in participants and more recently Henderson, Clemow, Massion, Hurley, Druker & Herbert (2012) reported beneficial effects of MBSR on spirituality and meaningfulness in early stage breast cancer patients. This finding is particularly important because 'Spirituality' is a core domain in the assessment of quality of life in oncology and its development may contribute to improvements in long term psychosocial adjustment (Peterman, Fitchett, Brady, Hernandez & Cella, 2002).

MBIs involve structured activities and exercises specifically designed to promote and enhance meditation self-efficacy but not all the participants were successful in this enterprise and the theme of 'Challenge' is of particular interest in this context. The challenge theme illuminated the factors that influence this pivotal goal of meditation self-efficacy and it has therefore provided clinicians with information about how the overall effectiveness of the program could be improved.

Although the growing body of effectiveness and efficacy studies on MBI has promoted a much better understanding of how the programs work, there has been no investigation of what factors have influenced participant engagement and retention on the program. It is however important to gain an understanding of how participant characteristics determine the program's effectiveness because without this understanding, MBI's will not realise their full potential in the combative role they occupy in an oncology setting. As noted by Shapiro, Brown, Thoresen & Plante (2011)

it is important to determine not only whether and how MBSR is effective but also for whom it is most effective (or ineffective). Until this is known little can be done to make it more effective for those who currently need it but cannot fully access it. Once investigations uncover the relationships between these participant characteristics and attrition rates, MBI program facilitators can start modifying the program accordingly. Such modifications might involve restructuring lessons, exercises and other MBI elements to accommodate different participants so that the initiation of individual, at home meditation practice, is maximised.

A Possible Mechanism of Action

The four themes identified in this review can be interpreted to provide an explanation of how the MBIs reduced, or modified, the psychological distress and coping difficulties (and produced other positive outcomes) of the cancer victims who participated in the 9 studies analysed in this review.

The Perceptual Shift theme described a process of profound transformation that included changes in the way participants related to their illness and the fears and anxieties that they had initially associated with it. A possible mechanism to explain how the fear provoking stimulus, e.g. the cancer diagnosis, came to lose its power to create fear and anxiety has been described by Holzel, Lazar, Gard, Schuman-Olivier, Vago and Ott (2011). These researchers argued that the process that operates in mindfulness, when participants expose themselves to a fear provoking stimulus, within the safe environment created by the MBI practice, is that the fear response is extinguished in much the same way as fear responses are extinguished in Exposure Therapy, a therapy that has been widely used in the treatment of anxieties and phobias (Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014).

The process hypothesised here is that the participants were guided by their mindfulness facilitators (who ensured participants felt they were in a safe and supportive environment) to attend to thoughts and realities that they had previously avoided, and as a consequence of this exposure to those unpleasant stimuli, they came to perceive them differently and their negative emotional responses subsequently extinguished.

As well as, and arguably because of, the extinction of fears and anxieties, participants became more empowered to cope with stressors as they arose, they came to understand that they had more control over their environments, including aspects of

their illnesses, and this resulted in more effective behavioural responses that contributed to positive thoughts and positive outlook.

Although exposure leading to extinction may explain how participants came to conquer their fears, and sometimes even embrace their diagnosis as a positive experience, there is the problem of explaining how participants found the personal strength to stop avoiding, and start consciously attending, to those fears. Given that they were required to attend to the very aspects of their environment that they were strongly motivated to avoid, e.g. fears and anxieties related to the disease itself; the stigma associated with it; fears and anxieties of the treatment side-effects; and, the sense of isolation experienced by cancer victims, it is important to identify a mechanism that empowered them sufficiently to confront and overcome these obstacles and the Connection theme provides that possible mechanism. The Connection theme described how, as a result of the group exercises, participants developed a sense of contact with others with whom they shared the common experience of their cancer illness; it also described an increasing connection with spirituality. The social support that emerged as a consequence of the shared bond with others and the personal strength that was felt from the increased sense of spirituality, which together transcended the illness, offers a plausible explanation of how participants were able to take the important step of attending to the feared stimuli, which in turn caused that fear to be extinguished. As well as the Connection theme offering a possible explanation based on the strength derived from increased feelings of social support and spirituality, there is also the possibility that social conformity played a role in determining that participants faced their fears, i.e. participants were probably influenced by the pressure to 'fit in', furthermore, this behaviour might have been reinforced because social conformity protects individuals from having strong negative emotions even when the outcomes are bad (Yu & Sun, 2013)

The theme of Challenge described the importance of participants being capable of managing practical and psychological demands related to the MBI programs; for example, attending to the present moment is an integral part of both the MBSR and MBCT programs and it is a skill that is acquired through practice, i.e. participants were required to do practice exercises which facilitated the acquisition of this skill (attending to events in the present moment). The MBI's worked in part because the participants had acquired the necessary skills and when they did not have those skills the programs were experienced as less effective. The theme of Challenge also described the

importance of other skills and abilities, e.g. having the necessary understanding, emotional stability, intention and attitude for experiencing success from the MBI.

The theme of Psychological well-being and quality of life described how participants came to feel empowered by their experience of the MBI; there was an acknowledgement that the MBI's had produced profound positive change and this association fuelled continued practice which ensured continued benefits were experienced, i.e. this theme described how positive feedback of the benefits of the MBI promoted continued practice and the ongoing developmental transformation associated with it.

Summary. The theory posited here is that the MBI's worked because an appropriate supportive environment was created (i.e. the Connection theme), and those participants who had the necessary mental, physical and psychological resources to complete the required exercises (the Challenge theme) were subsequently able to consciously pay attention, with the correct intention and attitude, to their fears, distress and anxieties. The participants exposure to those negative emotions resulted in the extinction of those emotions and this experience, i.e. an understanding that paying attention could neutralise strong negative emotions, led participants to reappraise many aspects of their belief systems causing significant changes in those belief systems, most notably they realised that they had the freedom to reflectively choose positive behaviours when previously they had reflexively adopted negative behaviours (Shapiro et al., 2006). This reappraisal of personal belief systems precipitated significant and positive personal transformations in those belief systems (the Perceptual Shift theme). The personal transformation and development that participants experienced fuelled improved mental and physical health, (the Psychological Wellbeing and Quality of Life theme) the recognition of which reinforced continued practice of mindfulness exercises.

Limitations

Meta-synthesis invariably produces findings that are at least three times removed from the experiences of the subjects in the synthesised studies - that is, the findings reflect a representation of the original researchers' representations and in the meta-synthesis another representation. While it could be argued that the inevitable loss of contextual and fine detail represents a loss of important information that was contained in the original studies, Britten, Pope, Donovan, Morgan & Pill (2002) argued that the most important contribution of qualitative studies arises from synthesising them

in studies such as this one. It is however, important to be vigilant regarding possible sources of error when interpreting findings from any study – the evidence needs to be carefully exmined. This review contained two levels of evidence: first, there were direct quotes from participating patients, which appeared in the nine research papers, and second, there were the interpretative, summary statements of the authors of those papers. Each of these levels has potential limitations arising from different types of bias, associated with both the respondents and researchers.

In relation to the first level of evidence, i.e. direct quotes from participating patients, what the participants said might have been, in whole or in part, determined by social desirability bias, which occurs as a consequence of the tendency people have to create a favourable image of themselves when responding to questions (Van de Mortel, 2008). In this review social desirability probably operated in at least two contexts, i. when participants wanted to be accepted or liked by the researcher who collected the information, and ii. when they wanted to be accepted or liked by other participants, for example, when they took part in focus groups. Equally participants might have been influenced by acquiescence bias, which is the tendency to agree with the researcher, or be positive about something to do with the researcher.

To an extent these different types of response bias can be controlled by the researcher but almost inevitably the methods used to collect information from participants, e.g. interviews, questionnaires, and focus groups, will have contributed to both types of response bias that were discussed above.

Another possible source of inaccurate information from respondents is response habituation (Groves & Thompson, 1970), which occurs when participants have been influenced in their responses by the tendency to provide similar answers to similar questions, this occurs more often when respondents are tired or experiencing low energy, i.e. not thinking too deeply about questions demands less energy and effort than focusing attention on any differences in meaning between two questions.

While all three types of response bias discussed above are very common, and therefore likely to have contributed to inaccuracies in the information collected in the 9 studies, habituation bias, is arguably of particular relevance to the participant sample in this review, i.e. as habituation bias occurs when people are fatigued and/or have low energy, it might have operated more for these people, who (because of their illnesses) were likely to be have been significantly more fatigued and have had lower energy levels, compared to a sample without a cancer diagnosis.

In relation to the second level of evidence, there are several types of researcher bias that may have operated, the most widely recognised of which is confirmation bias, which occurs when researchers selectively collect and interpret data in ways that support existing beliefs or hypotheses (Roulston & Shelton, 2015). Confirmation bias often involves the, usually unconscious, filtering of information so that only information consistent with the idea, belief or hypothesis (or that contradicts any competing hypothesis) is collected. For example, a possible source of confirmation bias that may have operated in the nine studies that were reviewed in the present study is related to the possible belief or expectation of the researcher, that the MBI would have some positive impact on stress and anxiety.

However diligent researchers were, it would have been extremely difficult for them to completely avoid being subjected to confirmation bias; furthermore, confirmation bias may have been (and probably was) facilitated by the errors/inaccuracies in the first level of evidence, e.g. it is plausible, and arguably highly probable, that some, and possibly a significant number, of the participant comments were influenced by the various types of response bias discussed earlier, hence, any interpretation of those comments, that accepted them on face value, would necessarily have produced unreliable evidence, with obvious implications for the conclusions of, and confidence that can be placed in, the reported results of the meta-synthesis completed in this review. Generalisations from this review are limited by the various types of bias that may have operated (and interacted) at both levels of evidence and the findings of this review must be viewed in that light.

Further limitations arise by virtue of the sample, i.e. participants in the identified studies were predominantly female and very little information was provided on the ethnic backgrounds and social status of the participants; these factors limit severely the generalisability of the findings.

Interpreting findings from studies that have adopted different epistemological perspectives is a contentious area; the issue that has attracted most attention is the problem of interpreting a synthesis of studies that have different theoretical structures and foci (Jenson & Allen, 1996). This meta-synthesis combined studies using different methodologies - however, the varying perspectives were considered as part of the data analysis and interpretation of the results. Sandelowski and Barroso (2002) argued that all studies may contribute to an emerging understanding and that analysing findings

generated from multiple theories and methods as well as different philosophical and methodological perspectives can enhance the credibility of the findings.

Conclusion

In summary, the results of this study indicate that participants developed the skills and had the experiences that MBSR was designed to deliver. Systematic reviews of MBSR in oncology have documented how the intervention is effective for improving mood, sleep, fatigue, psychological functioning, psychosocial adjustment, stress management, enhanced coping and well-being in cancer patients (Shennan, Payne & Fenlon, 2011), and the findings of this review are consistent with these findings. Findings from this meta-synthesis offer the clinician an integrated and more complete interpretation of findings on cancer patients' perceptions and experiences of MBIs than has previously been available; critical re-interpretations of the nine selected studies produced four themes that illuminated cancer patients' perceptions and experiences of MBIs; furthermore, these four themes were used to describe a possible mechanism by which the MBI's produced the beneficial health outcomes that were observed.

The 'Challenge' theme is of particular interest because it focuses attention on activities that some participants found challenging; for example, independent home meditation practice was reported as a challenging. Such difficulties in general may undermine the health and wellbeing impact of MBI's, and the challenge theme, by highlighting these areas of potential difficulties, provides insights regarding where strategies are needed for improving the effectiveness of MBSR. Further research to increase understanding of how participant characteristics influence MBI program effectiveness is warranted.

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Systematic Review Appendices

Appendix A: Systematic Review Protocol

A qualitative metasynthesis on the experiences of Mindfulness Based Stress Reduction therapy on cancer patients

Background

Almost half of cancer patients experience psychological distress and difficulty coping post-diagnosis. Given that the psychological trauma has not, until relatively recently, been addressed by orthodox medical interventions it is unsurprising to find that cancer victims have reported high levels of dissatisfaction with the care they have received (Ashbury et al., 1998). Fortunately, the situation is improving, and many oncologists and health professionals now recommend additional treatment protocols to address issues of emotional trauma, National Health Service guidelines suggest that Complementary therapies and psychological interventions should be integral to patient support. One of the most promising therapies in terms of modifying psychological distress and improving health related quality of life (HRQoL) among cancer patients is mindfulness (Carlson & Garland., 2005; Ledesma & Kumano., 2009). Working in the 1970s, Jon Kabat Zinn and his colleagues at the University of Massachusetts Medical Centre created MBSR, a practical psycho-educational and skills based therapeutic package that has become a standard CAM procedure for physician-referred, medical patient population with a wide range of diagnoses. Shennan et al.2010 conducted a systematic review of mindfulness-based interventions in cancer care and concluded that mindfulness approaches are a promising intervention in cancer care. The study recommended that further qualitative research be undertaken including research into different styles of mindfulness delivery. Although in recent years there has been some qualitative research published on mindfulness based interventions there is as yet no cumulative body of knowledge about, or theoretical understanding of mindfulness. According to Sandelowski et al., (1997) 'individual qualitative studies risk being lost as disparate isolated islands of knowledge without some attempt to sum them up' (p.367). The aim of qualitative meta-synthesis is to account for all important similarities and differences in language, concepts, images, and other ideas around a target experience Sandelowski et al., (1997). The aim of this

meta-synthesis is to describe and analyse the qualitative studies which examined cancer patients' perceptions and experiences of MBSR. This meta-synthesis has the potential to expand findings of existing qualitative studies on MBSR in ways that may be useful for improved clinical practice in oncology.

Review Question

What are cancer patients' perceptions and experiences of MBSR?
Search terms
(Cancer OR neoplas* OR tumor* OR tumour*) AND (Experience* OR perception* OR thought* OR feeling*) AND (Mindfulness OR "mindfulness based cognitive therapy" OR "mindfulness-based cognitive therapy" OR MBCT OR "mindfulness based stress reduction" OR "mindfulness-based stress reduction" OR MBSR) AND (Qualitative OR "qualitative research"). The search terms will be reviewed by the university librarian.*

Databases to be searched

Search to check if there is already an existing/on-going review:

National Institute for Health Research centre for research & dissemination

- PROSPERO

1. Six electronic databases to be searched:
    - PsycInfo
    - CINAHL
    - Scopus
    - Embase
    - Medline
    - Web of Science

HAND SEARCH

Mindfulness

Journal of Clinical Psychology

Reference lists of included studies

Researchers contacted for knowledge of unpublished data/ongoing studies

- Christina Shennan
- Velma Weitz
- Caroline Hoffman

Study Selection

Inclusion Criteria

- The study focused on cancer patients
- The study was peer reviewed
- Participants had experienced a mindfulness intervention
- Focus on patient perspectives and experience of mindfulness based intervention
- The study used qualitative methods
- The study was available in English
- Studies were conducted over the last 10 years (2003-2013)

Exclusion Criteria

- Examined non-patient perspectives
- Used quantitative research methods
- Theoretical or methodological articles
- Dissertations and book chapters

Search Procedure

Studies for the inclusion of the review will be selected by the lead reviewer (SE) and second reviewer. (SS) The reference software package Endnote will be used to manage searches.

The lead reviewer (SE) will screen out studies that are not available in English and those that were published before 2013. The lead reviewer (SE) will screen all titles and the

second (SS) and third reviewer (GF) 20% and 40% respectively. The following steps will be used.

- Title scan
- Reading abstracts and / or reading the full title

Hand searches on the selected studies and recent editions of journals will also be carried out by the lead reviewer and authors of relevant studies in the field to be contacted to acquire and recent or unpublished studies.

Study Quality Assessment

The tool to assess quality will be the Critical Appraisal Skills Programme (CASP) (Public Health Resource Unit, 2006). This assesses:

- Appropriate research design
- Sampling
- Data collection
- Reflexivity
- Ethical issues
- Data analysis
- Findings
- Value of research

Data extraction

Details of the studies agreed to be suitable for the review will be added onto Endnote and double-checked. All details in the spreadsheet will be examined by the lead and second reviewer highlighting any errors in extraction or discrepancies in interpretation between the reviewers. Any differences will be discussed with the opinion of the third reviewer invited when necessary.

Data synthesis

The studies will be synthesised following the steps of metasynthesis (Sandelowski and Barroso,2003,2007). The following will be applied

- Formulate the research question
- Conduct a systematic literature search
- Screen and select appropriate research articles
- Extract the results
- Analyse and synthesize qualitative findings
- Maintain quality control
- Present findings.

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Appendix B: Quality Criteria

Journal details:

Screening Questions

1. **Was there a clear statement of the aims?** **( ) Yes ( ) No ( ) Unclear**

Consider:
– what the goal of the research was
– why it is important
– its relevance

2. **Is this study qualitative research?** **( ) Yes ( ) No ( ) Unclear**

Consider:
– if the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants

……

Is it worth continuing? **( )Yes ( ) No ( ) Unclear**

……..

Detailed Questions

Appropriate research design

3. **Was the research design appropriate to address the aims of the research?** **( ) Yes ( ) No ( ) Unclear**

Consider:
– if the researcher has justified the research design (e.g. have they discussed how they decided which methods to use?)

Sampling

4. **Was the recruitment strategy appropriate to the aims of the research?** **( ) Yes ( ) No ( ) Unclear**

Consider:

– if the researcher has explained how the participants were selected

– if they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study

– if there are any discussions around recruitment (e.g. why some people chose not to take part)

Data Collection

5. **Were the data collected in a way that addressed the research issue?** **( ) Yes ( ) No ( ) Unclear**

Consider:

– if the setting for data collection was justified

– if it is clear how data were collected (e.g. focus group, semi-structured interview etc.)

– if the researcher has justified the methods chosen

– if the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews were conducted, did they use a topic guide?)

– if methods were modified during the study. If so, has the researcher explained how and why?

– if the form of data is clear (e.g. tape recordings, video material, notes etc.)

– if the researcher has discussed saturation of Data

Reflexivity (research partnership relations/recognition of researcher bias)

6. **Has the relationship between researcher and participants been adequately considered?** **( ) Yes ( ) No ( ) Unclear**

Consider whether it is clear:

– if the researcher critically examined their own role, potential bias and influence during:

– formulation of research questions

– data collection, including sample recruitment and choice of location

– how the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Ethical Issues

7. Have ethical issues been taken into consideration? **( ) Yes ( ) No ( ) Unclear**

Consider:

– if there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained

– if the researcher has discussed issues raised by the study (e. g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)

– if approval has been sought from the ethics committee

Data Analysis

8. Was the data analysis sufficiently rigorous? **( ) Yes ( ) No ( ) Unclear**

Consider:

– if there is an in-depth description of the analysis process

– if thematic analysis is used. If so, is it clear how the categories/themes were derived from the data?

– whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process

– if sufficient data are presented to support the findings

– to what extent contradictory data are taken into account

– whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Findings

9. Is there a clear statement of findings? **( ) Yes ( ) No ( ) Unclear**

Consider:

– if the findings are explicit

– if there is adequate discussion of the evidence both for and against the researcher's arguments

– if the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst.)

– if the findings are discussed in relation to the original research questions

Value of Research

10. How valuable is the research? ( ) Yes ( ) No ( ) Unclear

Consider:

– if the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature?)

– if they identify new areas where research is necessary

– if the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

LIST OF ABBREVIATIONS USED

- BREATHE British Research and Training in Health Psychology Initiative
- CAM Complementary Alternative Medicine
- CASP critical appraisal skills programme
- CBT Cognitive behavioural therapy
- CDTQ "cut down to stop" , or "cut down to quit"
- COPD chronic obstructive pulmonary disease
- CPA Community Practice Association
- DH Department of Health
- DPH Director of Public Health
- HAD Health Development Agency
- HBM Health Belief Model
- HCP Health Care Professionals
- HRQoL health related quality of life
- ICPC The International Classification of Primary Care
- MBCT Mindfulness-Based Cognitive Therapy
- MBI Mindfulness Based Intervention
- MBSR Mindfulness -Based Stress Reduction
- MRC Medical Research Council
- MUPS medically unexplained physical symptoms
- MYMOP Measure Yourself Medical Outcome Profile
- NCCAM National Centre for Complementary and Alternative Medicine
- NCCIH US National Centre for Complementary and Integrative Health
- NCSCT National Centre for Smoking Cessation and Training
- NICE National Institute of Clinical Excellence
- NIHCE National Institute of Health & Clinical Excellence
- NIH National Institute of Health
- NNL Neighbourhood Nurse Leads
- NRT Nicotine Replacement Therapy
- PBC Practice Based Commissioning
- PCM Process Consultancy Model
- PCT Primary Care Trust
- PEC Professional Executive Committee
- PGI Patient-Generated Index
- PTG Post Traumatic Growth
- QoL Quality of Life
- RCT Randomised Controlled Trial

- RFE Reason for Encounter
- SEIQoL Schedule for the Evaluation of Individual Quality of Life
- SES Socio Economic Status
- SSSCHSP Stop Smoking Services in Community Health Services Project
- TCM Traditional Chinese Medicine
- TCMA Traditional Chinese Medicine Acupuncture
- TPB Theory of Planned Behaviour
- TRA Theory of Reasoned Action
- UKNSCC UK National Smoking Cessation
- VAK Visual-Auditory-Kinaesthetic
- WHO World Health Organisation
- WICC WONCA International Classification committee